A COMPARATIVE ANALYSIS OF HEARING IN CARTILAGE OSSICULOPLASTY AND PARTIAL OSSICULAR REPLACEMENT PROSTHESIS OSSICULOPLASTY

Dissertation submitted to

THE TAMILNADU DR. MGR MEDICAL UNIVERSITY

in partial fulfillment of regulations for the award of the degree of

M.S, DEGREE BRANCH – IV OTORHINOLARYNGOLOGY

COIMBATORE MEDICAL COLLEGE, COIMBATORE

THE TAMILNADU DR. MGR MEDICAL UNIVERSITY,

CHENNAI

MAY 2019

DECLARATION

I solemnly declare that the dissertation entitled **"A COMPARATIVE ANALYSIS OF HEARING IN CARTILAGE OSSICULOPLASTY AND PARTIAL OSSICULAR REPLACEMENT PROSTHESIS OSSICULOPLASTY"** has been done by me at the Coimbatore Medical College Hospital , Coimbatore during 2017 – 2018 under the guidance and supervision of **Prof. Dr. A.R.ALI SULTHAN, M.S.ENT, DLO.**

This dissertation is submitted to the Tamilnadu Dr. M.G.R.Medical University, towards partial fulfillment of regulations for the award of M.S.DEGREE (BRANCH IV) in Otorhinolaryngology.

Place :

Date :

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CERTIFICATE

This is to certify that this dissertation titled **"A COMPARATIVE ANALYSIS OF HEARING IN CARTILAGE OSSICULOPLASTY AND PARTIAL OSSICULAR REPLACEMENT PROSTHESIS OSSICULOPLASTY"** submitted by **Dr.Vineetha.K** appearing for M.S.(E.N.T) degree (Branch IV – Otorhinolaryngology) examination in May 2019 is a bonafide record of work done by her under my guidance and supervision in partial fulfillment of regulations of the Tamilnadu Dr.M.G.R.Medical University Chennai. I forward this to the Tamilnadu Dr.M.G.R. Medical University , Chennai, Tamilnadu, India

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Name of the Candidate:		**Dr. Vineetha .K**
Course	:	**MS (ENT) Post Graduate**
Period of Study	:	**1 year**
College	:	**Coimbatore Medical College & Hospital.**
Dissertation Topic	:	**A Comparative analysis of hearing outcome between cartilage and partial ossicular replacement prosthesis ossiculoplasty.**

The Ethics Committee, Coimbatore Medical College has decided to inform that your Dissertation Proposal is accepted and you are permitted to proceed with the above Study.

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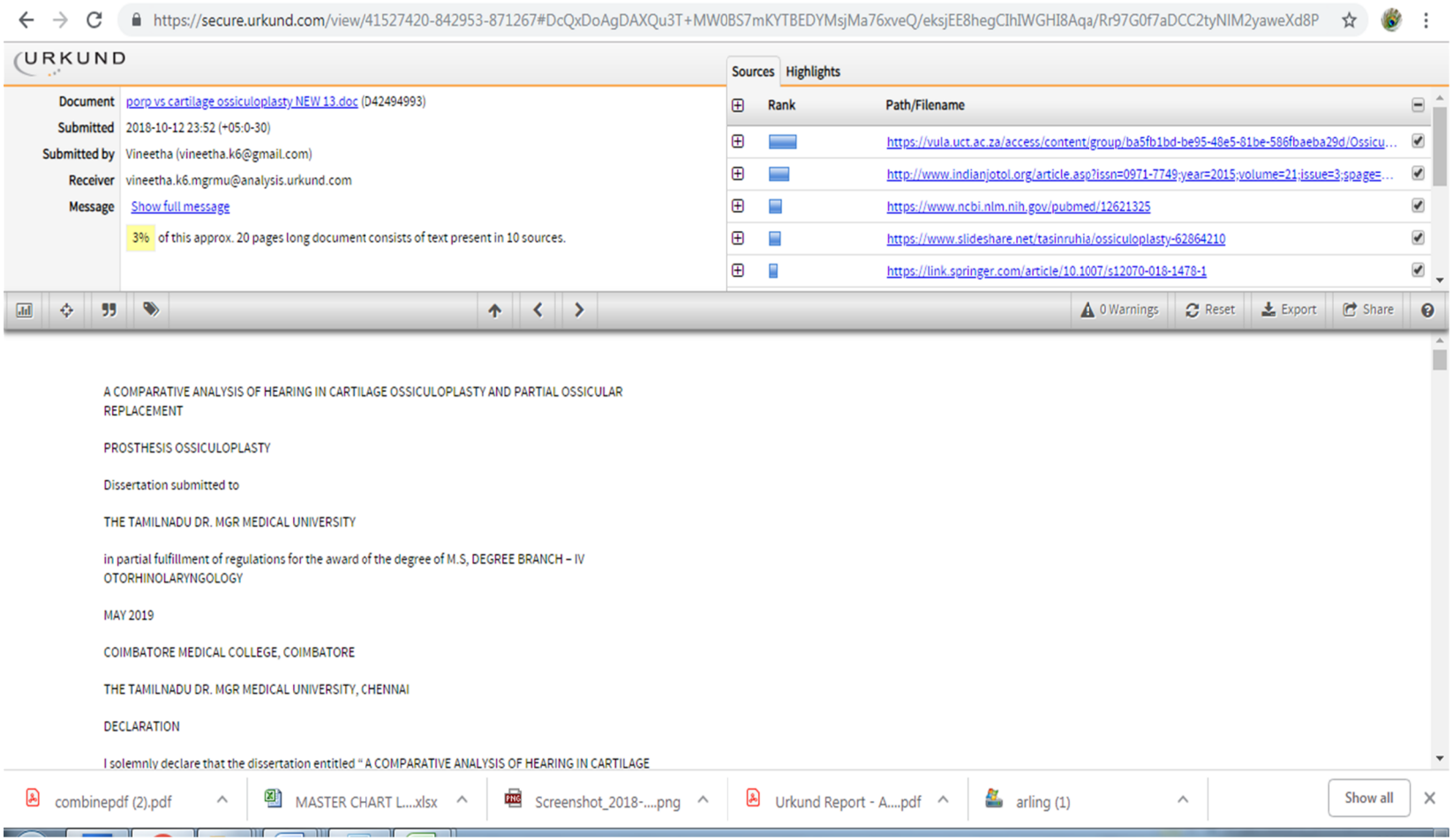
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Dr.Vineetha.K

ABBREVATIONS USED

CP	Central perforation
CSOM	Chronic suppurative otitis media
CT	Computed Tomography
dB	Decibel
EAC	External auditory canal
HA	Hydroxylapatite
HL	Hearing Loss
PORP	Partial Ossicular Replacement Prosthesis
PTA	Pure Tone Audiogram
TM	Tympanic Membrane
TORP	Total Ossicular Replacement Prosthesis

TABLE OF CONTENTS

INTRODUCTION

Chronic suppurative otitis media is a common cause of conductive hearing loss in developing countries. Despite advances in public health and medical care, it continues to be prevalent. According to WHO, CSOM was considered as the most common cause of persistent mild to moderate hearing impairment among children and young people in developing countries. It is even more significant because chronic otitis media is a common cause of preventable deafness.

The World Health Organisation has indicated that a prevalence rate of chronic suppurative otitis media greater than 4 % in a defined population is indicative of a massive public health problem requiring urgent attention The prevalence in India being 7.8 %.[1]

Chronic suppurative otitis media is a long standing infection. Among the two types of chronic suppurative otits media, tubotympanic and atticoantral, the former is characterized by central perforation in the pars tensa surrounded by residual tympanic membrane and the latter involves posterosuperior part of middle ear cleft.

Chronic otitis media is a leading cause for deafness, which is due to tympanic membrane perforation and ossicular erosion resulting from chronic inflammation of middle ear cavity.

Erosion of Incudostapedial joint with intact malleus is the most common ossicular defect encountered in both tubotympanic and atticoantral type of chronic otitis media. Austin estimates that in about 60% cases malleus and stapes suprastructure are intact [2]. Pure tone audiogram shows an hearing impairment of more than 40dB in patients with ossicular erosion.

Therefore the quest is now focussed towards attaining a near normal neomembrane with continuous ossicular chain and a post operative middle ear status which functionally bears close resemblance to the normal state.

Goals of surgery for chronic ear disease are eradication of the disease and reconstruction of the sound conduction mechanism. Numerous ossiculoplasty techniques have been used to reconstruct the ossicular chain.

Ossiculoplasty material should be ideally biocompatible, stable, safe, affordable and easily available. Autograft, homograft and synthetic prosthesis can be used for ossicular reconstruction. In our study we used conchal cartilage autograft and partial ossicular replacement prosthesis for ossicular reconstruction.

The purpose of this study is to evaluate our experience with cortical mastoidectomy and ossicular reconstruction for ossicular discontinuity at the incudostapedial joint, with intact stapes suprastructure and malleus, using cartilage autograft and PORP and comparing their hearing results

postoperatively. We assessed air bone gap reduction achieved following surgeries in both groups and the rate of extrusion of biomaterial used.

In our study we are finding a better option for ossicular reconstruction hence patient will be having a better hearing postoperatively.

AIM & OBJECTIVES

1. To assess hearing outcome following autologous cartilage ossiculoplasty and PORP ossiculoplasty in patients with chronic otitis media, tubotympanic type with incus bone erosion alone.

2. To compare the above results and to assess hearing gain in both condition.

3. To assess air bone gap reduction following cartilage and PORP ossiculoplasties.

4. To compare extrusion rate in both groups

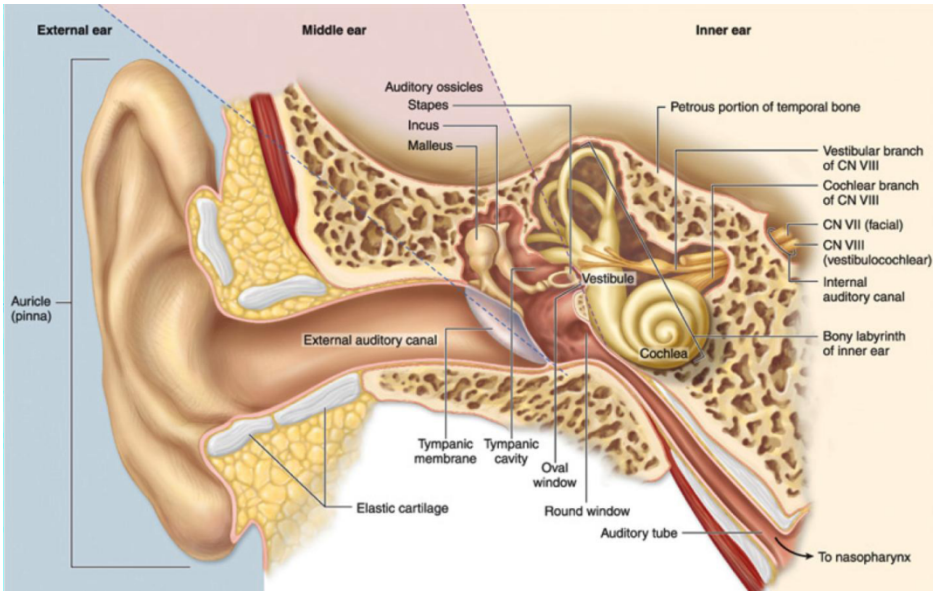
REVIEW OF LITERATURE

Chronic suppurative otitis media, is defined as chronic inflammation of middle ear space resulting in long-term or more often permanent changes in tympanic membrane like perforation, atelectasis, retraction pocket or cholesteatoma. It is one of the common causes of conductive deafness, and continues to be widely prevalent in our country. Chronic suppurative otitis media can be of two types; tubotympanic and atticoantral type. Former is associated with permanent central perforation which can be presented with recurrent bouts of otorrhoea (active CSOM), dry but permanent tympanic perforation (inactive CSOM), which is an previously discharging ear ceased discharging without any probability of resumption in near future and healed state.

The latter, atticoantral type presents either with attic perforation, postrosuperior retraction, cholesteatoma and granulations. Ossicular erosion and complications are more with this and hence considered as dangerous type. Generally patients with tympanic perforations which continue to discharge mucoid material for periods of 6 weeks to 3 months[3] despite medical treatment are recognized as CSOM cases. The WHO definition requires only 2 weeks of otorrhoea, but otolaryngologists tend to adopt a longer duration, more than 3 months of active ear discharge[4].

Incidence of chronic otitis media is higher in poor socioeconomic class, poor nutrition and in rural population. It affects both sexes and all ages. Prevalance surveys show that the global burden of illness due to chronic suppurative otitis media involves 65-300 million individuals - 60% of whom suffer from significant hearing impairment. In India, the proportion of patients with CSOM having hearing impairment is higher – 77%. The global burden of hearing impairment can be potentially reduced by 4/5th if CSOM is effectively tackled. Chronic otitis media cases which are not resolved by conservative management with aural toilet, oral and topical antibiotics should be considered for surgery.

ANATOMY OF AUDITORY APPARATUS



PINNA:

Pinna is formed by a single piece of yellow elastic cartilage which determines contour of pinna. Shape shows interindividual variability which proves its multicomponent embryological origin. It protects the entrance to the ear canal. Gathers sound waves and aids in sound localization especially higher frequencies. Pinna itself amplifies sound by 5-6 dB.

EXTERNAL AUDITORY MEATUS:

External auditory canal extends as a continuation from auricular cartilage from concha to tympanic membrane. EAC is 24mm long with anterior wall 6mm longer than posterior wall. It is "S" shaped and comprises 2 parts:-

(1) Outer- Cartilaginous part - continuation of cartilage of pinna, 8mm in length. Skin of cartilagenous canal is thick and contains ceruminous and pilosebaceous glands that secrete wax and have hair follicles.

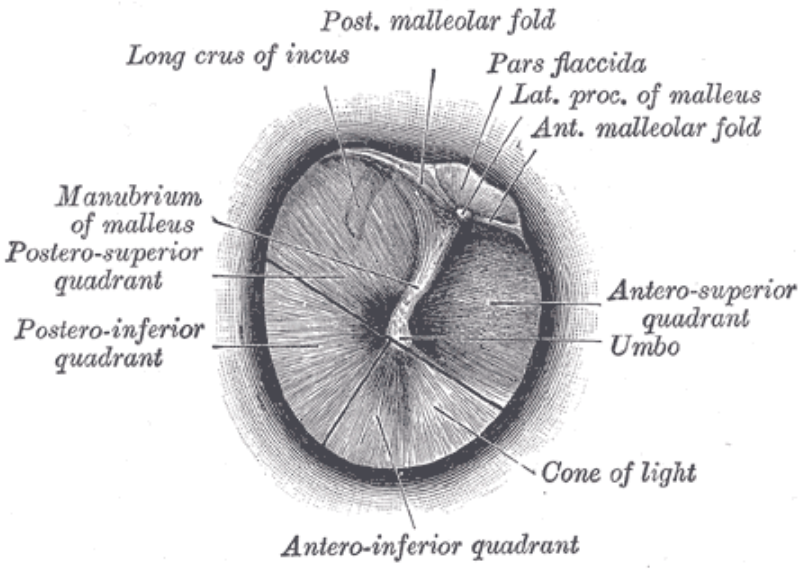
(2) Inner- Bony part-16mm in length, devoid of hair and ceruminous glands.

It acts as the pathway for the auditory signal to reach cochlea.

TYMPANIC MEMBRANE:

Tympanic membrane is a three-layered thin membrane which originates from three germ layers. An adult tympanic membrane is about 9-10mm tall, 8-9mm wide,1mm thick and subtends an angle of 55^{o} with the floor of external auditory canal. Central part tensed inwards at tip of malleus to form umbo and

peripherally the fibrous annulus anchors tympanic membrane into the tympanic sulcus.



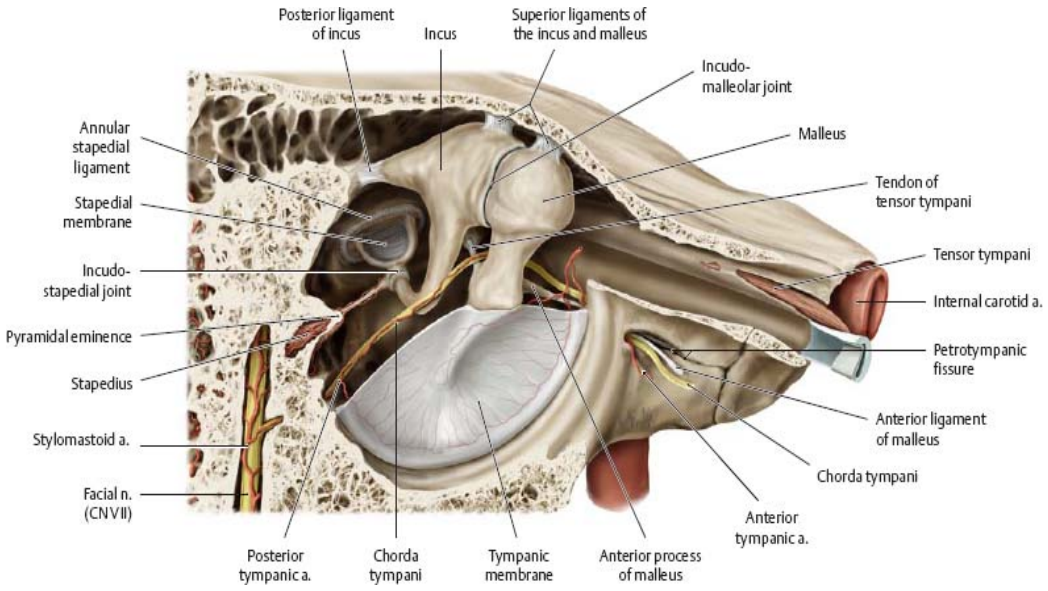
Tympanic membrane is a trilaminar structure, lateral surface is formed by squamous epithelium. Mucosal epithelium forms medial surface. Middle fibrous layer encloses - radial, circular and parabolic layers. The outer radial fibrous layer inserts on the manubrium of malleus. Deeper circular fibrous layer is arranged circumferentially, both integrates to form the tympanic annulus. The part of tympanic membrane located superior to the mallear folds lacks a fibrous layer, known as PARS FLACCIDA OR SHRAPNEL'S MEMBRANE and is attached superiorly to the notch of Rivinus, and the 3 layered inferior part is known as PARS TENSA.

MIDDLE EAR CLEFT

Middle ear cleft consists of middle ear (tympanic cavity), eustachian tube, aditus and mastoid air cell system. It acts as “miniature lung”. Mastoid air cells, tympanic cavity and tympanic membrane are lined by mucosal epithelium revealing common origin from tubotympanic recess.

MIDDLE EAR

Middle ear, also known as tympanic cavity is an air filled chamber lined by mucous membrane. It is divided into 3 parts.The part of middle ear above the level of neck of malleus is epitympanum. The Mesotympanum lies between the two horizontal lines drawn at lower and upper edges of pars tensa. The Hypotympanum lies below the level of bony ear canal. Protympanum lies anterior to mesotympanum surrounding eustachian tube orifice.



Anterior wall :-

-Lower third consists of a thin plate of bone which separates cavity from internal carotid artery.

-Middle third consists of two openings - Eustachian tube orifice and canal for Tensor tympani muscle.

-Upper third forms anterior epitympanum.

Posterior wall :-

It lies close to mastoid air cells. Superiorly there is aditus, which connects epitympanum to mastoid antrum. The key anatomic features are pyramidal eminence and chordal eminence. Pyramidal eminence gives attachment to tendon of stapedius, which in turn gets attached to neck of stapes. Facial recess is a shallow depression in posterior wall of tympanic cavity which is bounded by pyramid with facial nerve medially and chorda tympani laterally and fossa incudis with short process of incus superiorly.

Medial wall :-

Medial wall, otherwise known as surgical floor of middle ear is formed by labyrinth. Promontry is the most prominent part which lies over the basal turn of cochlea. Medial wall features 3 depressions :-

-oval window,round window and sinus tympani.

1) Fenestra Vestibuli or Oval window lies in the posterosuperior aspect of medial wall. Oval window is closed by foot plate of stapes and communicates with the vestibule medially.
2) Fenestra Cochleae or Round window or is an opening sealed by a thin membrane called secondary tympanic membrane and lies posteroinferior to the promontory allowing communication between middle and inner ear.
3) Sinus tympani lies medial to pyramid and is bounded by subiculum inferiorly and ponticulus superiorly.

Anterior to oval window there is a hook like projection called pocessus cochleariformis on which tensor tympani muscle tendon takes a hook and turns laterally to get attached to neck of malleus. It forms landmark for 1st genu of facial nerve.

Roof :-

Tegmen tympani,formed by both squamous and petrous portion of temporal bone.

Floor :-

Formed by a thin tympanic plate which separates hypotympanum from the dome of jugular bulb.

EUSTACHIAN TUBE

Also known as auditory tube or pharyngotympanic tube, which connects nasopharynx with middle ear cavity. It ventilates middle ear cleft, maintains pressure within the middle ear by balancing it with outside pressure. Also it clears off mucus secretions of middle ear. Tubal dysfunction will results in chronic otitis media.

CONTENTS OF MIDDLE EAR

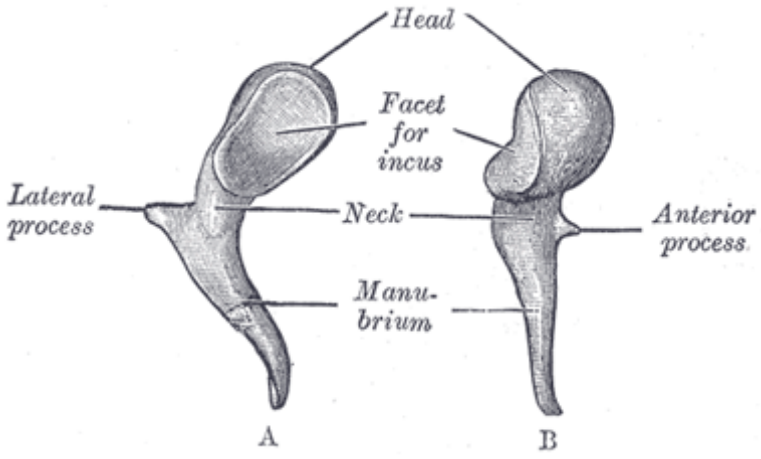
- Air
- 3 Ossicles :- Malleus, Incus, Stapes
- 2 Intratympanic muscles :- Tensor tympani, Stapedius
- 2 Nerves :-Chorda tympani, Tympanic plexus
- Mucosal folds and ligaments
- Blood vessels

OSSICLES:

They are 3 in number and transmits sound from external ear to inner ear.

Malleus

Malleus is the most lateral of ossicles . It is about 8 to 9 mm long. It lies between the tympanic membrane and incus.



1. Head – oval shaped and lies in the attic. It articulates posteriorly with the Incus by a small facet. It gives attachment to superior and lateral malleolar ligaments.

2. Neck – narrow contracted part beneath head of malleus, which gives attachment to tendon of tensor tympani.

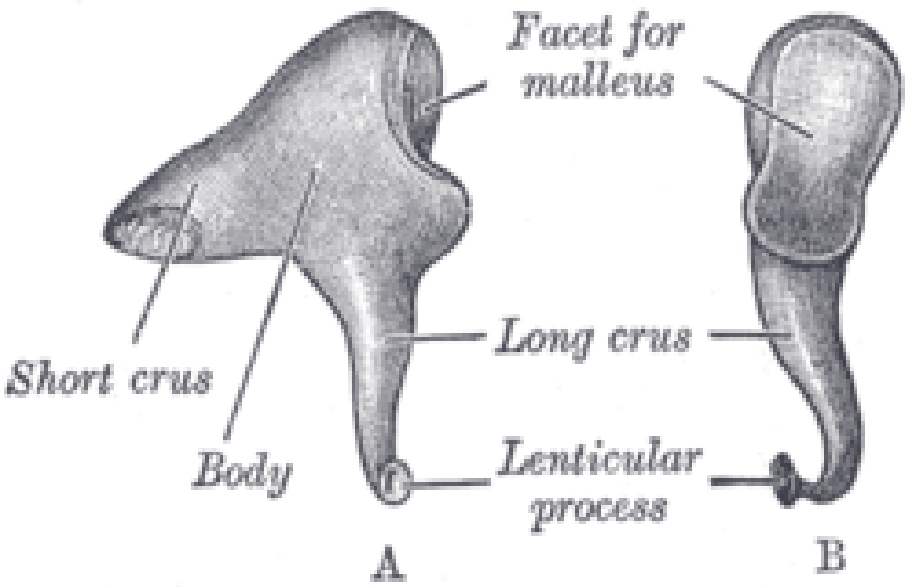
3. Anterior process – directed forward to petro tympanic fissure and connected to it by the anterior malleolar ligament.

4. Lateral process – It is a projection from upper end of manubrium and is attached to the malleolar folds.

5. Handle – directed downwards, backwards and medially. It's lateral margin is connected to upper half of the tympanic membrane.

Incus

Largest of the three ossicles**.** It is anvil shaped and articulates with the head of malleus anteromedially and stapes inferomedially.



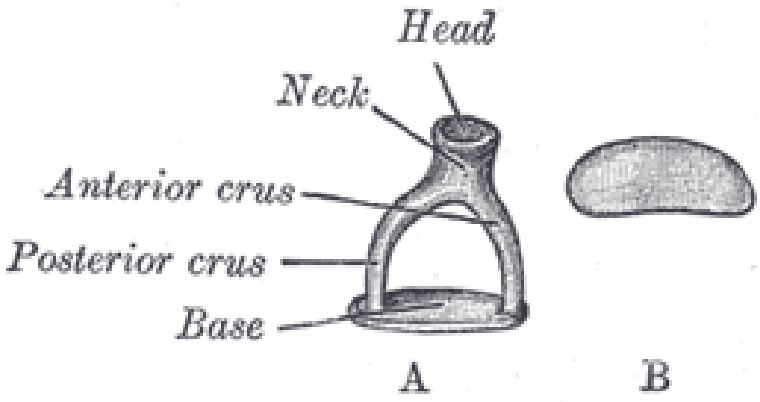
1. Body – articulates with head of malleus and to which superior incudal ligament gets attached.

2. Short process – It is directed backwards and lies in fossa incudis.

3. Long process – projects downwards into the cavity and is parallel with the handle of malleus. Its tip is bulbous and known as lenticular process, which is directed medially articulates with stapes head.

Stapes

This is the medial most and smallest of the 3 ossicles. It has following parts:-



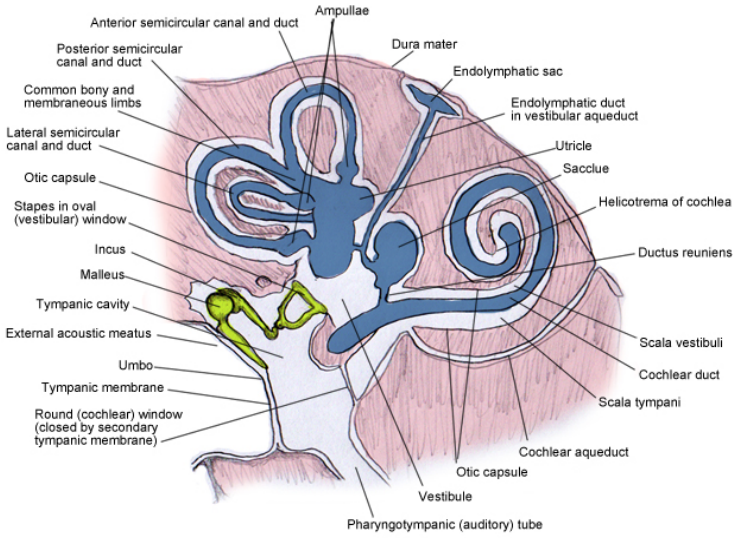
1. Head – It has a small concave facet for articulation with lentiform process.
2. Neck – narrowest part,where tendon of stapedius inserts.
3. Crura – anterior and posterior crura, anterior crura is shorter and less curved. Both attached to the foot plate.
4. Foot plate –oval shaped and fits into the oval window by an annular ligament.

The mucous membrane lines the bony walls of tympanic cavity and extends to cover the ossicles and supporting ligaments to form mucosal folds which along with ossicular chain, partitions the middle ear. Mesotympanic and epitympanic regions are separated by

- superior malleolar
- lateral malleolar

- lateral incudal
- medial incudal
- inter ossicular

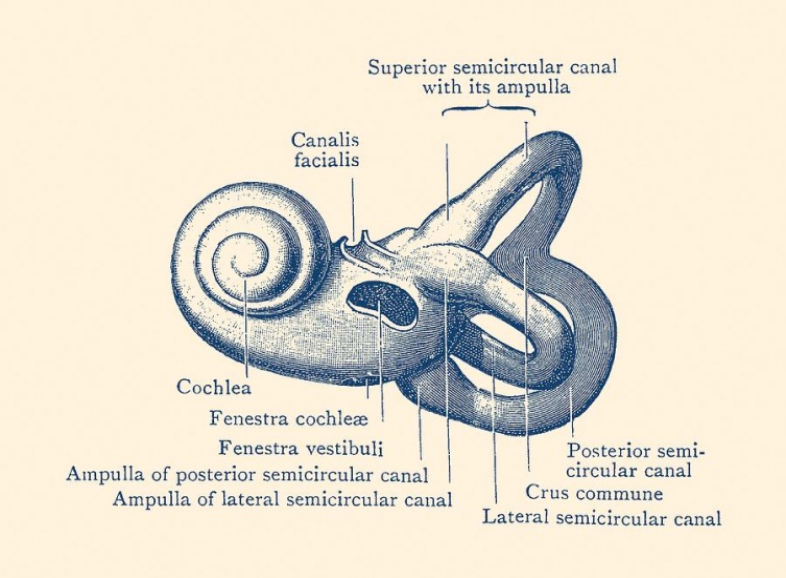
INNER EAR



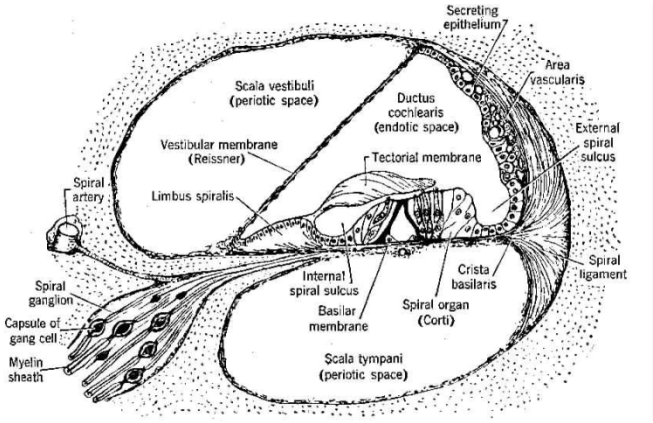
The inner ear is also known as labyrinth. The bony labyrinth, which is a bony cavity in temporal bone houses the sensory organs and soft tissue structures of inner ear. Its bone has three layers-outer periosteal layer, inner endosteal layer and a middle layer consisting of enchondral and intrachondrial bone.

Inner ear consists of :-

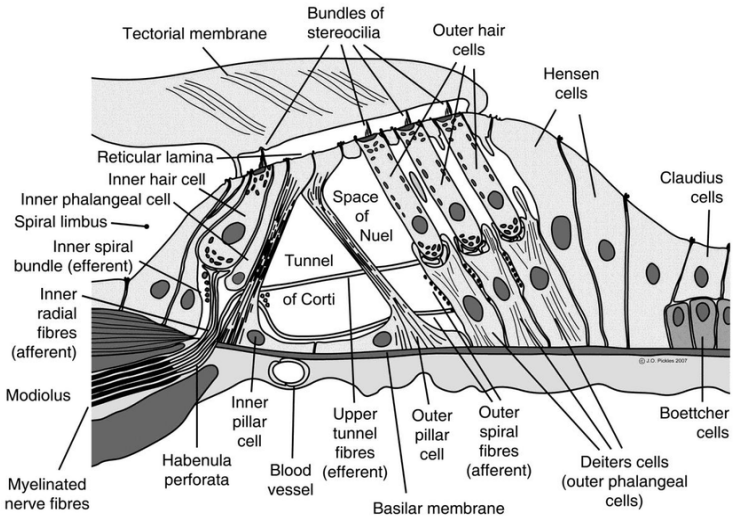
- Cochlea
- Semicircular canals
- Vestibule



The cochlea spirals two and half turns about its central axis, modiolus. The osseous spiral lamina winds around modiolus along with basilar lamina, which separates the scala tympani from the cochlear duct (scala media). Adjacent turns of cochlea are separated by an inter scalar septum.



ORGAN OF CORTI



It is the auditory receptor organ of mammalian cochlea. It comprises of two types of sensory receptors, inner and outer hair cells. Both hair cell types contain hair bundles that consists of highly organized actin - filled stereocilia that are graded in height. Hair bundles are mechanoreceptive organelles of hair cells.Each and every hair cells sit on supporting cells. The inner and outer pillar cells delineate the area between inner and outer hair cells and frame the tunnel of corti. Along its entire length organ of corti is covered by tectorial membrane.

This acellular structure is medially attached to the spiral limbus and connects to the hair bundles of outer hair cells[5].

MECHANISM OF HEARING IN HUMAN BEINGS

Sound is a form of energy that propagates in the form of waves. Speed of sound in air is 343m/s. The sound frequencies audible to humans range from about 20-20,000 Hz.

Pinna collects waves from environment and passes to external auditory canal. Sound waves reaches tympanic membrane, passed to oval window through ossicles. Sound waves reaches cochlea and from there to auditory nerve.

PINNA:-

Pinna – concha system catches sound over large area and concentrate it to smaller area of external auditory canal. It facilitates locating sounds, especially at higher frequencies.

EXTERNAL AUDITORY MEATUS:-

It is the pathway for transmitting the auditory signal. It acts as a tube resonator. It transmits high - frequency sounds (2000-4000 Hz) and generally between 500- 4000Hz. It cuts off unwanted frequency hence better speech discrimination.

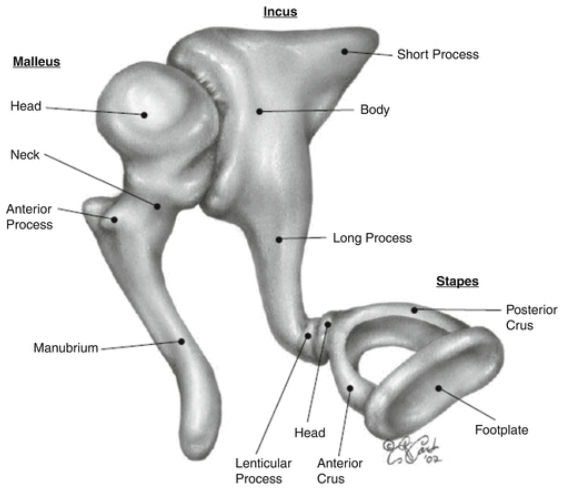
It increases the pressure at the eardrum end in a frequency sensitive way and also protects inner ear from direct injury from sounds.

TYMPANIC MEMBRANE :-

Tympanic membrane receives sound vibrations from outer air and transmits it to the auditory ossicles which are converted into mechanical movement.

AUDITORY OSSICLES:-

- Malleus, incus, stapes



From eardrum ossicles pick up tympanic membrane pressure movement and convey it to the inner ear through oval window. They transform air pressure into mechanical movements.

OVAL WINDOW:-

Interface between middle and inner ear. It transmits mechanical movements transmitted from ossicles into the perilymph of the scala vestibuli of cochlea.

EUSTACHIAN TUBE :-

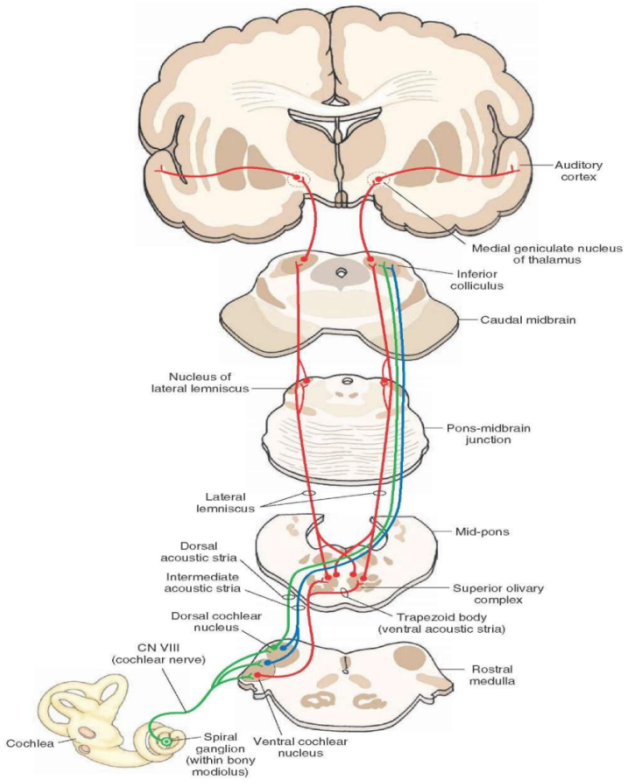
It equalizes air pressure differences on either side of tube between outer environment and middle ear.

INNER EAR :-

Transduction of sound from mechanical to electrical signals occur in Organ of corti in inner ear. Mechanical waves vibrates basilar membrane, stimulating hair cells. This results in change in membrane potential in hair cells and signals are transmitted to cochlear nuclei, which is the first relay station for all ascending auditory information. Second order neurons pass mainly to the opposite side of the brain stem to terminate in the superior olivary nucleus.

The auditory pathway ascends upwards through lateral leminiscus. But many bypasses this nucleus and travel on to the inferior colliculus, where all or almost all the auditory fibres synapses. From there the pathway passes to the medial geniculate nucleus. Finally the pathway proceeds by way to the auditory radiations to auditory cortex.

From cochlea the sound pathway is as follows.



Pathologies affecting structures from auricle to oval window results in conductive hearing loss.And pathology affecting cochlea and auditory pathway upto cortex will cause Sensorineural hearing loss.

ESSENTIAL OF MIDDLE EAR OSSICLES FOR HEARING

The middle ear acts as a impedance transformer, converting air borne sound of large amplitude but small force into large force low amplitude vibrations which is suitable for driving cochlear fluids.

Impedance matching by middle ear system:-

- Hydraulic action of tympanic membrane
- Lever action of ossicles
- Catenary lever (curved tympanic membrane effect)
- Phase differential effect

HYDRAULIC LEVER

The effective vibratory area of tympanic membrane ($55mm^2$) is more than stapes oval window surface area ($3.2mm^2$) .So force produced by sound concentrated over small area amplifying pressure on oval window.

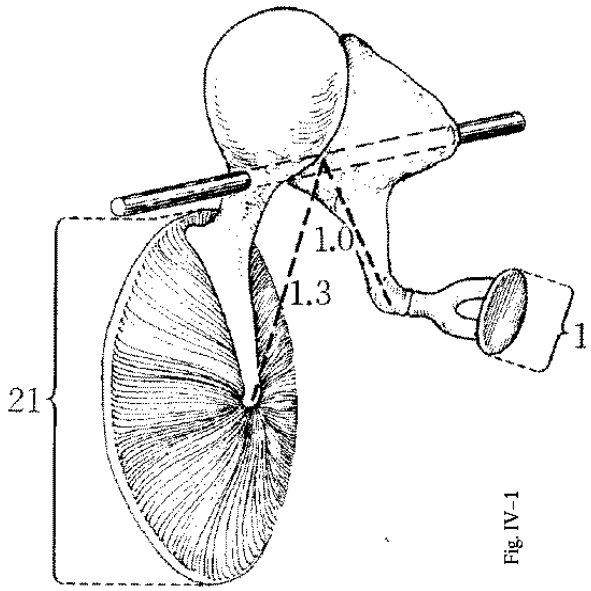
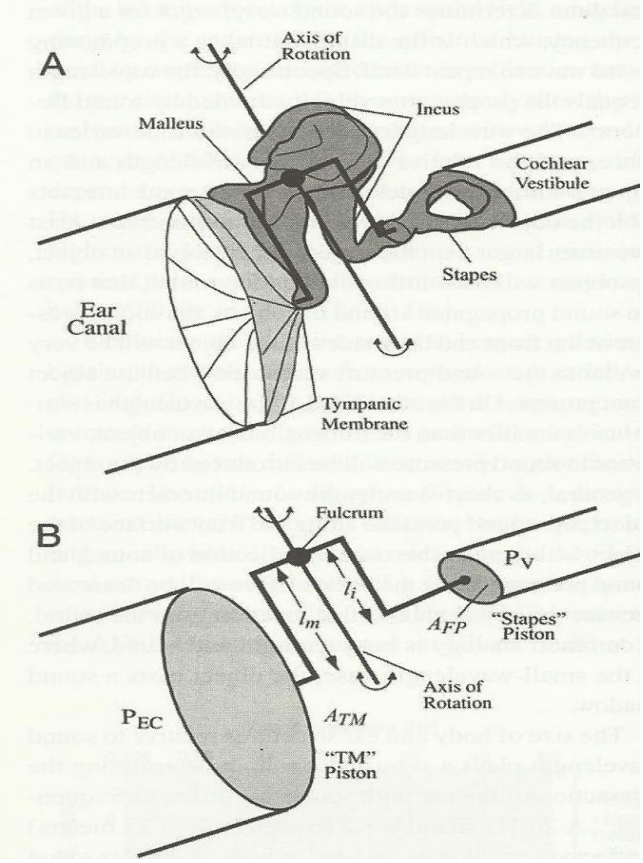


Fig. IV–1

OSSICULAR LEVER

The Malleus incus assembly moves together, difference in length of manubrium of Malleus and long process of incus. Results in a gain of 1.3:1 [6].



MECHANICS OF THE TYMPANO OSSICULAR SYSTEM

$A_{TM:}$ Area of tympanic membrane.

A_{FP} :Area of stapes footplate

P_{EC} :Pressure in the external canal.

$P_{V:}$Pressure in the vestibule

l_m:Length of malleus handle.l_i : length of incus long process

CATENARY LEVER

The tympanic membrane is rigidly attached to annulus resulting in increase in energy at handle of Malleus. Since the annulus is fixed, the sound energy concentrate at centre and thereby handle of Malleus perceives the sound.

Bekesy calculated the effective vibrating surface of the tympanic membrane area to the stapes footplate area to be 17:1 and the lever effect of the ossicular chain to be 1.3 :1. The total increase of pressure at the oval window is 22 times (17 x 1.3).This sound pressure transformer mechanism of the normal ear equates to approximately 27 dB gain.

For this mechanism to effectively function , the presence of the following pre requisites are essential : an intact, mobile tympanic membrane, ossicular chain integrity and ideal mobility, middle ear cavity of normal volume and ventilation.

OSSICULAR COUPLING

It is the gain in pressure of sound obtained when sound travels from tympanic membrane through the ossicles. It depends on frequency and hence not 34 decibels always; like 20 decibels with 250 to 500 Hz and 25 decibels at 1000 Hz. Thereafter it decreases 6 decibels for every octave. This is because at

higher frequencies the tympanic membrane vibrates at different portions and also at higher frequencies ossicular chains slips.

ACOUSTIC COUPLING

It is another mechanism for sound stimulation of inner ear. Since oval window and round window are separated by few millimetres and also different orientation of each window relative to the tympanic membrane acoustic sound pressure acting on oval and round window are not identical. In normal ears, the pressure between both windows are negligible, but is significant in case of some diseased and operated ears where it is enough to cause hearing loss. Acoustic coupling is 60 dB lesser than ossicular coupling.

STAPES COCHLEAR INPUT IMPEDANCE

This indicates factors impairing movement of foot plate of stapes over oval window thereby increasing the impedance and hearing loss.

MIDDLE EAR AERATION

Normally middle ear contains air. Sound conduction impairs when there is inadequate air or air is replaced by liquid or soft tissue.

These above mechanisms are even more relevant in this study as disturbances in them are encountered in the following aspects: large central perforation, ossicular discontinuity, a reduced middle ear space.

MECHANISM OF HEARING LOSS IN TYMPANIC MEMBRANE PERFORATIONS :

When a defect occurs in the tympanic membrane, sound protection of the round window is lost, and there is a tendency for the sound waves to reach both the round window and oval window at the same moment. This cancels the resultant movements of the perilymph. When the perforation is small, this effect is small. But in case of larger perforations, the transformer ratio further reduces, the cancelling effect of sound on the unprotected round window rises producing upto a loss of 40 to 45dB.

OSSICULAR PATHOLOGY IN CHRONIC OTITIS MEDIA

In chronic otitis media, ossicles can be either fixed or in discontinuity.

The causes of Ossicular fixation are:-

1. Malleus head ankylosis. The reason is idiopathic.
2. Scar bands
3. Ossicular tympanosclerosis secondary to healing .

The causes for Ossicular discontinuity are:-

1. Trauma
2. Erosion by chronic otitis media
3. Erosion by cholesteatoma

Ossicles eroded in order of frequency are:-

1. incudostapedial joint (lenticular process of incus is most commonly eroded)
2. stapes crurae
3. body of incus
4. manubrium [7].

In a study conducted in 2015 July, they recruited 211 patients with chronic otitis media. Among that, ossicular chain discontinuity was evident in 66 (23.6%) ears. The most frequently impaired ossicle was the incus. It was found eroded in 62 (22.2%) cases and absent in 1 (0.4%) case. In majority of the cases observed erosions were localized to the lenticular process ie; in 35 (12.5%) ears and the long process in 27(9.6%)ears. Hence, incudal erosion was observed to be the most prevailing ossicular pathology in cases of chronic otitis media[8,9]. Malleus was the most resilient middle ear ossicle and was respected in more than 95% of cases. In remaining 5%cases, erosion affects head of the malleus mainly and spares handle. This might be attributed due to the firm attachment of the handle to the tympanic membrane which acts as a barricade and allows adequate blood flow to the handle.

The stapes was secure in 248 (88.9%) ears and its superstructure was involved in 31 (11.1%) cases[10,11].

MECHANISM OF OSSICULAR EROSION

It is hypothesized that ossicular damage in chronic otitis media is induced by an active phenomena of osteoclastic osseous resorption rather than by a passive avascular necrosis[12]. The suggested mechanism for bony erosion is by excessive formation of inflammatory mediators like, cytokines including TNF - alpha, interleukin-2, prostaglandins, neurotransmitters, platelet derived growth factor, fibroblast growth factor and nitric oxide. In the tympanic cavity these mediators induces hypervascularisation, hyperaemic decalcification (halisteresis), osteoclast activation and bony resorption resulting in ossicular destruction. TNF - alpha also induces granulation tissue by producing neovascularisation. The duration of the inflammatory process and its vicinity to the ossicular chain are factors which appear to be the most harmful for the ossicles [13,14]. The factors that may explain that the incus lenticular and long processes being more vulnerable are possibly their tenuous blood supply, noticeable bone marrow, and their exposure to the external milieu especially in posterior perforations[15,16].

PRE OPERATIVE ASSESSMENT OF OSSICULAR PATHOLOGY

(1)Clinical examination

- otoscopic examination or under microscopic examination
- to ruleout congenital anomalies in ear and examining external auditory canal
- Status of the tympanic membrane and middle ear structures if seen

(2) CT scan of temporal bone will give information regarding

- Extent of middle ear pathology (cholesteatoma)
- Tympanic cavity, Malleus fixity, Ossicular chain status , Otosclerosis
- Inner ear anatomy and anomalies

(3) Pure Tone Audiogram

Ossicular discontinuity is suspected when the conductive hearing loss more than 40dB in PTA.

In a study published in Indian Journal Of Otolaryngologist published in 2012 it has been mentioned that, 20 patients who underwent ossicular reconstruction with autologous incus was studied retrospectively and the mean pre-operative pure tone average was 49.18 dB. The minimum hearing loss being 45 dB and the maximum value being 64 dB HL[17].

Carrillo et al. published a study aiming to identify preoperative audiometric patterns in patients with chronic otitis media that could predict the presence of complete ossicular discontinuity before primary surgery . The authors noted a strong correlation between ABG greater than 40 dB at 4 kHz and complete ossicular discontinuity[18].

Preoperative findings may suggest either a complete or an incomplete ossicular discontinuity, but the status of the ossicular chain can only be truly identified intraoperatively [19].

Austin's classification of ossicular chain defect [20].

Incus absent in all cases and tympanic membrane reconstruction required in all cases.

TYPES	OSSICULAR CHAIN STATUS
0	M+ I+ S+
A	M+ S+
B	M- S+
C	M+ S-
D	M- S-
E	Isolated loss of malleus handle
F	Isolated loss of stapes suprastructure
G	Ossicular head fixation
H	Stapes fixation

About 40 - 90% of tympanoplasties done will require middle ear ossicular chain reconstruction[21]. For cases with intact, defective incus and/or malleus but intact stapes type II and III tympanoplasties were the choice of ossiculoplasty according to the Wullstein classification in 1956 [22,23].

The term tympanoplasty was introduced in 1953 by Wullstein. Tympanoplasty is a procedure to eradicate disease in middle ear and to reconstruct hearing mechanism in chronic otitis media ear. Tympanoplasty can be considered the final step in the surgical conquest of conductive hearing loss

and represents the culmination of over 100 years of evolution of surgical procedures on the middle ear to improve hearing.

According to Wullstein classification, in Type III tympanoplasty both malleus and incus are absent hence graft is placed directly over stapes head. Myringostapediopexy produces a shallow middle ear and columella effect.

Ossiculoplasty is defined as restoring of hearing mechanism by establishing functional osicular chain between tympanic membrane and oval window.

OSSICULOPLASTY – HISTORY AND EVOLUTION :

Chronic middle ear infections (otitis media) damage the middle ear and lead to the development of conductive hearing loss. Surgery is the treatment of choice for chronic otitis media. In general, there are two aims of this approach. The first is to clear the infection by removing abnormal tissue and allowing the postsurgery cavity to heal. The second aim is to improve hearing by reconstructing the sound transmission apparatus, i.e., the eardrum, the ossicular chain and the air- -filled cavity within the temporal bone[24].

Ossiculoplasty was introduced soon after introduction of tympanoplsasty which made great advancement in physiological functioning .

In 1957, Hall and Rytzner performed first ossicular reconstruction with autologous ossicular bone in a case of otosclerosis over stapes suprastructure.

For cases with incus long process erosion , Bell in 1958,removed incus and transposed malleus attached to tympanic membrane on to stapes head - tympanomalleostapediopexy. Jongkees and Grippaudo reported osteitis in incus and malleus removed from chronic suppurative otitis media patients and stressed that failure of control of infection in such cases is due to osteitis and suggested avoidance in ossicular reconstruction. Realizing the need House, Patterson and Linthicum ,1966 introduced incus allograft. Kerr and Smyth conducted study on macroscopic and histological appearance of allografts and compared with autograft ,and found histologically both are similar.Guilford found that malleus-stapes interposition is more stable and effective than tympanic membrane -to- stapes head interposition.

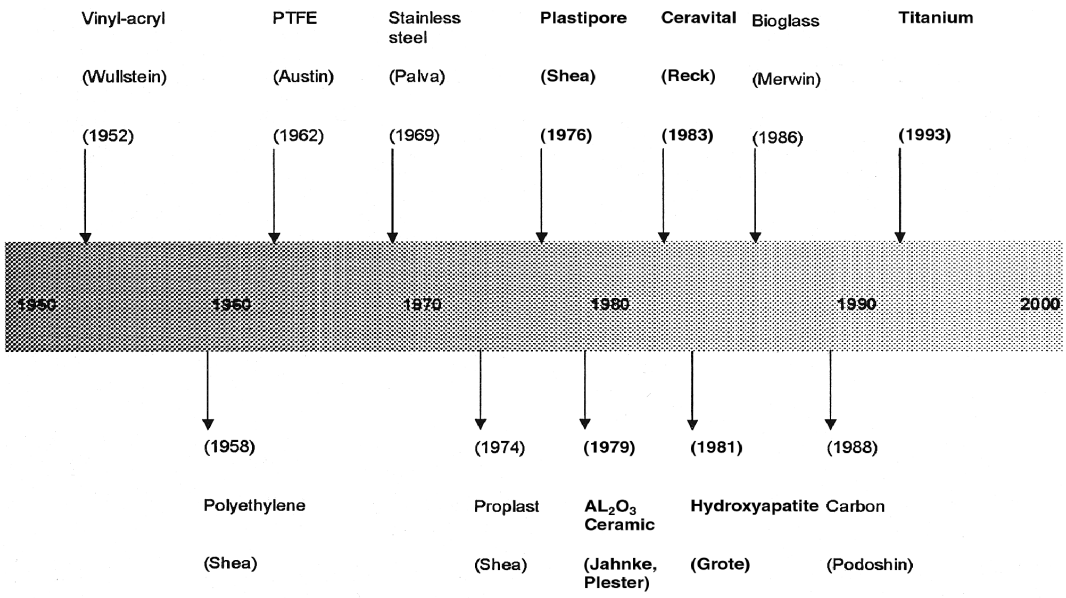
Wehrs developed notched incus autograft /allograft technique to fit it into stapes head.

Utech introduced sculptured auricular cartilage autografts and Jansen found autologous tragal cartilage and autologous or preserved allogeneic nasal septal cartilage suitable for ossicular reconstruction.

BIOMATERIALS

Also known as alloplastic materials, broadly subdivided into 4 groups :-

Biotolerant, Bio - inert, Bioreactive,Bioactive



First report of using alloplastic material in ossiculoplasty was made in 1952, when Wullstein used an oval strut of vinyl-acrylic 'palavit' as an acoustic transmitter between the mobile footplate and the tympanic membrane graft. Poor results with this material quickly caused him to abandon its use[25].

Austin introduced polytetra fluoroethylene (PTFE) in 1962 and in 1969 Palva reported about metallic implants.But both found to cause absorption at ossicular interfaces and spontaneous rejection. The interest in alloplastic materials in ossiculoplast was rekindled with the introduction of Proplast® in 1974 and Plastipore® in 1976 by Shea[26,27]. Plastipore was the first commercialised alloplastic material.

Partial ossicular replacement prosthesis (PORP) is done when incus bone erosion present with intact stapes suprastructure. Total ossicular replacement prosthesis (TORP)ised when stapes suprastructure is absent .

An aluminium oxide ceramic (Al2O3) ossicular prosthesis was introduced by Jahnke and Plester into clinical practice in 1979[28]. Cartilage interposition is recommended between the prosthesis and the tympanic membrane. The most popular alloplastic material to date is hydroxylapatite (HA) or calcium triphosphate. It is a bioactive ceramic that resembles the mineral matrix of bone. The clinical results of hydroxylapatite in middle-ear reconstruction was first reported by Grote in 1981[29]. Branemark in the 1970s established Titanium (Ti) as an excellent biocompatible material [30].

In a study conducted in 2005 comparing titanium and polycel total ossicular replacement prosthesis , successful hearing achieved in 64.4% of patients with titanium and 65% of patients with a Polycel prosthesis. Improvement in speech reception threshold was 11.5 dB in the titanium group and 13 dB in the Polycel group. In other words, there was no significant difference between the two groups. In addition, air-bone gap improvement after ossiculoplasty was 11.2 dB in the patients with a titanium prosthesis and 12.4 dB in the Polycel group[31].

Ugo Fisch classified Ossicular defects seen in chronic otitis media in accordance with expected hearing outcomes post operatively.He anticipated post operative air bone gap according to pre operative status of ossicular chain.

ABG	Pre op status of ossicles and mastoid
<10 dB	Malleus: Handle intact Incus: Absent Stapes: Intact
<20 dB	Malleus: Handle intact Incus: Absent Stapes: Fixed /no superstructure
<30 dB	Open/closed cavity mastoidectomy Malleus: Absent Incus: Absent Stapes: Mobile/fixed/mobile footplate

In a comparative study done with incus transposition versus titanium PORP ossiculoplasty in 2005,the extrusion rate was 4% with PORP and 1% for incus. Postoperative air bone gap was 25.5 dB in incus group and 16.9 dB in titanium group. They concluded titanium as well tolerated material of choice when incus is not usable [32].

House[33] in the year 2001 conducted a retrospective analysis of 1210 consecutive ossicular reconstructions with HydroxylApatite and Plastipore PORPs (n = 650) or TORPs (n = 560) . Closure of the ABG to within 20 dB was 63% among that 68% of PORPs, 58% of TORPs. Hearing results were

better for cases who had not had previous surgery. Overall extrusion was 4%, with no difference between HydroxylApatite and Plastipore, but statistically extrusion rate was lower when cartilage used. House's study reinforces the importance of placing a cartilage cap between prosthesis head to reduce chances of extrusion.

In the year 2001,Iurato[34] investigate hearing results from ossicular reconstruction in Austin-Kartush type A patients.

At 12 months follow-up, success was shown to be 84% vs 82% for incus interposition versus allograft (ceramics or HA) PORP. He demonstrated his own series of patients and success rate of homograft ossiculoplasty was 85% .Hearing was stable over 3 years post-op.In his study no extrusions or displacements of his autografts has been mentioned.

Ho [35] in the year 2003 reported on retrospective chart reviews on patients who had undergone ossiculoplasty using titanium middle ear implants. 64% and 45% of patients achieved air-bone gap less than 20 dB with PORP and TORP respectively. With the placement of cartilage graft interposed between the prosthesis and the tympanic membrane, no extrusions were observed.

Neff [36] in the year 2003 studied 18 patients who underwent tympanoossiculoplasty with a titanium TORP. Hearing results showed 89% surgical success. The average follow-up time was 8 months (range, 2-21

months). The results compare favourably with his own results using a porous polyethylene TORP in which 67% had success. No extrusions were seen in their short follow up time.

Rondini-Gilli [37] in the year 2003 reported on 100 patients who received a HydroxylApatite PORP (n=65) or TORP (n=35). Extrusion or displacement of the implants occurred in 10% of cases. These displacements were more common when no cartilage cap was placed. The results were not reported as successful closure less than 20 dB ABG. In addition to an absent stapedial arch with type 3 tympanoplasty, a radical mastoidectomy and a previous tympanoplasty were related to poorer auditory results.

Hillman [38] in the year 2003 published a retrospective study. Review of 84 patients undergoing tympanoplasty with the Plastipore prosthesis and 53 with titanium. There was 1 extrusion in the titanium group. There was an additional single incidence of prosthesis failure in the titanium group. 60% of patients had postoperative air-bone gap of 20 dB or less in the Plastipore group. In the titanium group, 45.3% achieved a 20 dB or less air-bone gap.

In a study done by Otologic Medical Group,Los Angeles; they reviewed 564 tympanoplasties done over eight years.In all cases tragal cartilage has been used for establishing sound pressure transfer mechanism. Conductive deficit was reduced to 20dB or less in 67% and 10dB or less in 40% cases. And also there was no instance of cartilage resorption and 1 case of extrusion [39.]

A retrospective case series was conducted in tertiary referral center Marseille, France.There 25 patients undergone incudostapedial rebridging ossiculoplasty between 2009 and 2013. Among that 15 cases were chronic otitis media. Three different materials used for ossiculoplasty- hydroxyapatite cement, incus remnant, and partial/ total ossicular replacement prostheses. Pure tone audiogram done before and after ossiculoplasty and the patients followed up for 12 months. Results in cases of chronic otitis media; residual air-bone gap was 17dB with PORP, 12dB with TORP, and 20dB with incus transposition [40].

MATERIALS AND METHODS

This study was carried out in the Department of ENT, Coimbatore Medical College Hospital.

Study period

January 2017-september 2018

Study design

Prospective cohort study of patients undergoing ossiculoplasty in our hospital.

Study population

Consisted of patients who attended the ENT outpatient department at Coimbatore medical college hospital with chronic otitis media and ossicular erosion.

Sample size

40

Financial support

Self

INCLUSION CRITERIA :

1. Age between 15 years and 50 years.
2. All cases of Chronic suppurative otitis media –safe type with ossicular erosion .
3. Pure tone audiogram with more than 40dB hearing loss.
4. All cases with ossicular damage as diagnosed by otoendoscopy and per operative finding.
5. Intact suprastructure of stapes
6. Conductive hearing loss
7. Good Eustachian tube function evidenced by diagnostic nasal endoscopy
8. No other external ear, middle ear or inner ear pathology.

EXCLUSION CRITERIA :

1. Chronic otitis media –unsafe type or with complication
2. Mixed hearing loss
3. Stapes fixation
4. Only hearing ear

5. History of previous ear surgery.
6. State of middle ear mucosa – unhealthy or polypoidal
7. Congenital ear anomalies
8. Patient not reporting for follow up
9. Pregnant and lactating mother
10. Uncontrolled systemic diseases which affect the healing process.

A total of 40 patients attending the outpatient department who met the above criteria were selected. After eliciting their complaints and history, they were subjected to detailed clinical examination of the ear, nose and throat. The size , site of perforation , status of middle ear mucosa , status of the ossicles were examined using otoscope and findings documented. Clinical findings were confirmed by otoendoscopic examination. Tuning fork tests were done using 256 Hz, 512 Hz and 1024 Hz tuning fork and findings recorded.

All patients were subjected to pure tone audiometry, and graphical recordings of their hearing thresholds were made. Pure tone averages and air bone gap were calculated. Plain x ray mastoids both sides lateral oblique view were taken for each patient. Diagnostic nasal endoscopy was done to rule out nasal and nasopharyngeal foci of infection and to assess the pharyngeal end of the Eustachian tube. Computed tomography was taken for each and every

patient before surgery to know about middle ear and ossicular status. Also to ruleout cholesteatoma and congenital anomalies.

Systemic examination and investigations were done to assess fitness for surgery. Patients were explained about the surgery and informed written consent was obtained.

Patients were assigned into two groups randomly, each consisting of 20 patients. One group underwent cartilage tympanoplasty and PORP ossiculoplasty in the other group.

PROCEDURE ADOPTED

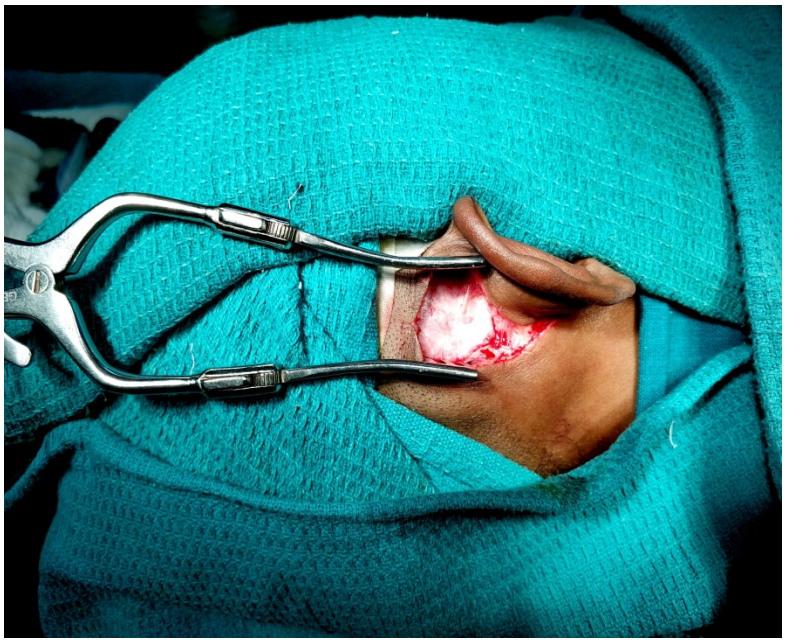
After doing all these investigations and obtaining informed written consent for surgery and participating in our study, all patients were operated under general anesthesia.

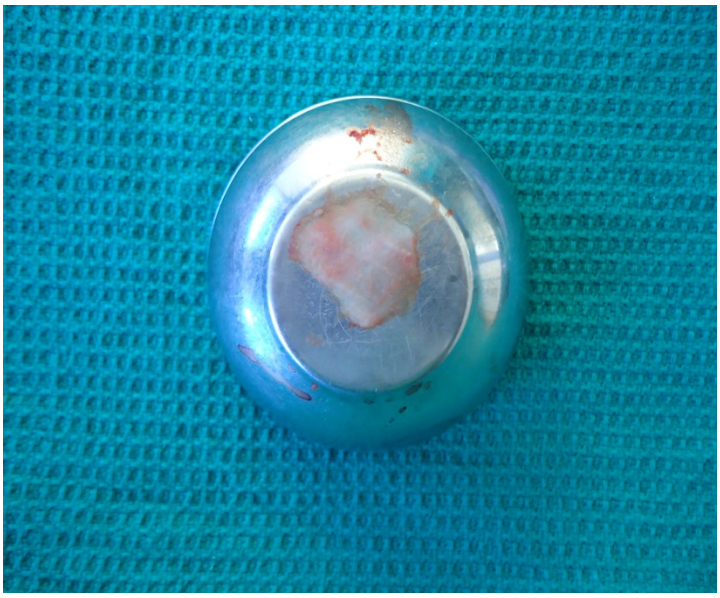
MASTOIDECTOMY

After area preparation, sterile draping and local infiltration with 2% lignocaine and 1 in 200000 adrenaline given in post auricular and external auditory canal. Ear canal wash done with betadine.

Sir William Wilde post auricular incision made.

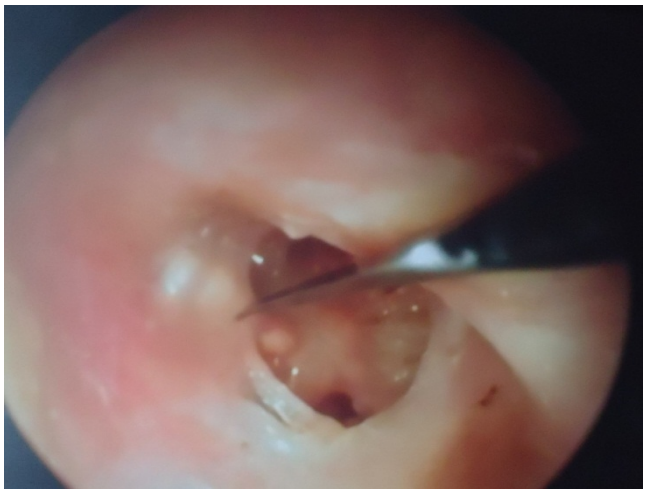
Incision deepened superiorly and temporalis fascia graft harvested





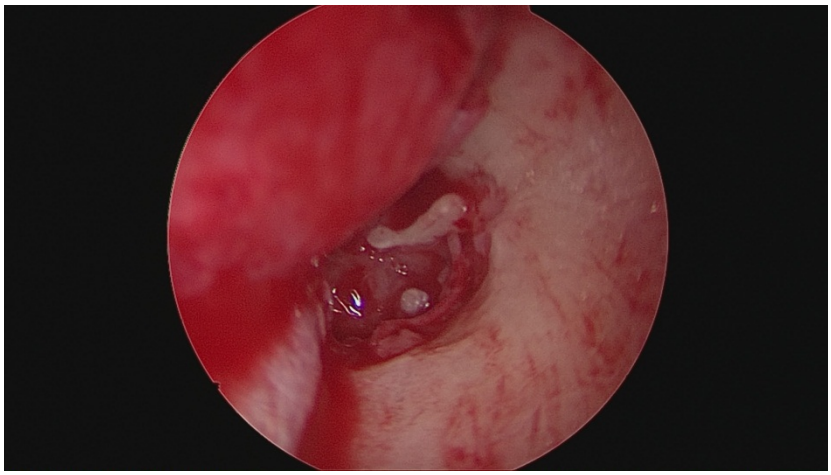
A T-shaped incision is made through the soft tissues and periosteum elevated.

Posterior meatotomy done and tympanic membrane visualized. The margins of the perforation were freshened.



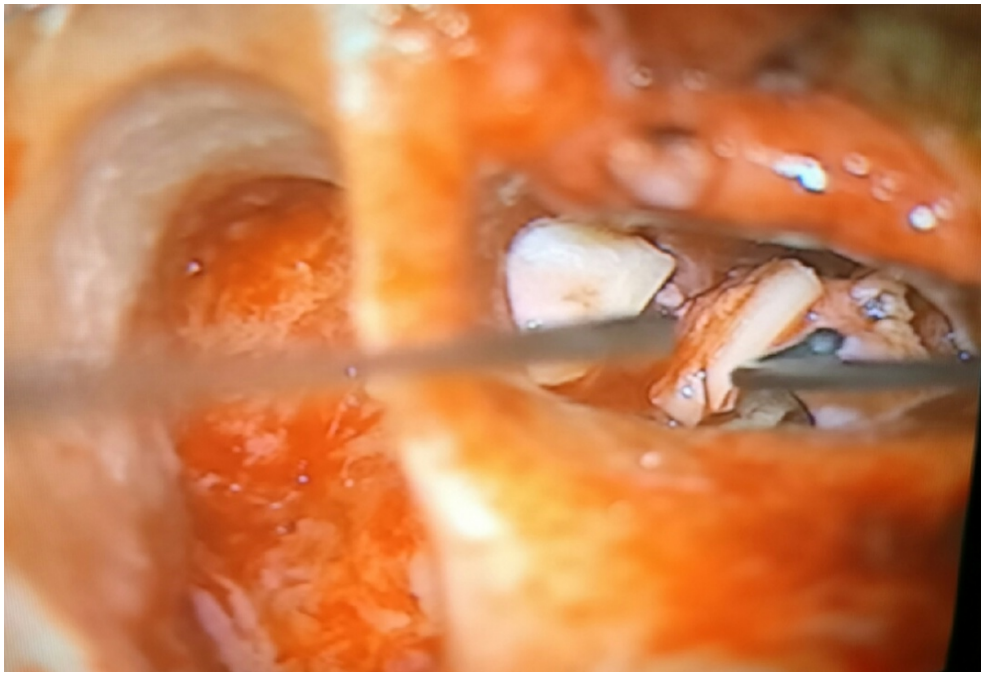
The meatal skin is now incised about 5 to 6 mm from the edge of the tympanic membrane 6 o clock and 12 o clock positions and tympanomeatal flap elevated. Status of middle ear and ossicular chain inspected .

The mastoid is opened through McEwans triangle with a drill. Mastoid antrum entered and disease clearance done. Aditus widened and patency ensured. Ossiculoplasty was done in the primary sitting itself.



AUTOLOGOUS CARTILAGE GRAFT

Autologous conchal cartilage harvested from the the inferior part of concha. The height of cartilage is adjusted so that it gets fitted exactly between head of stapes and neomembrane.

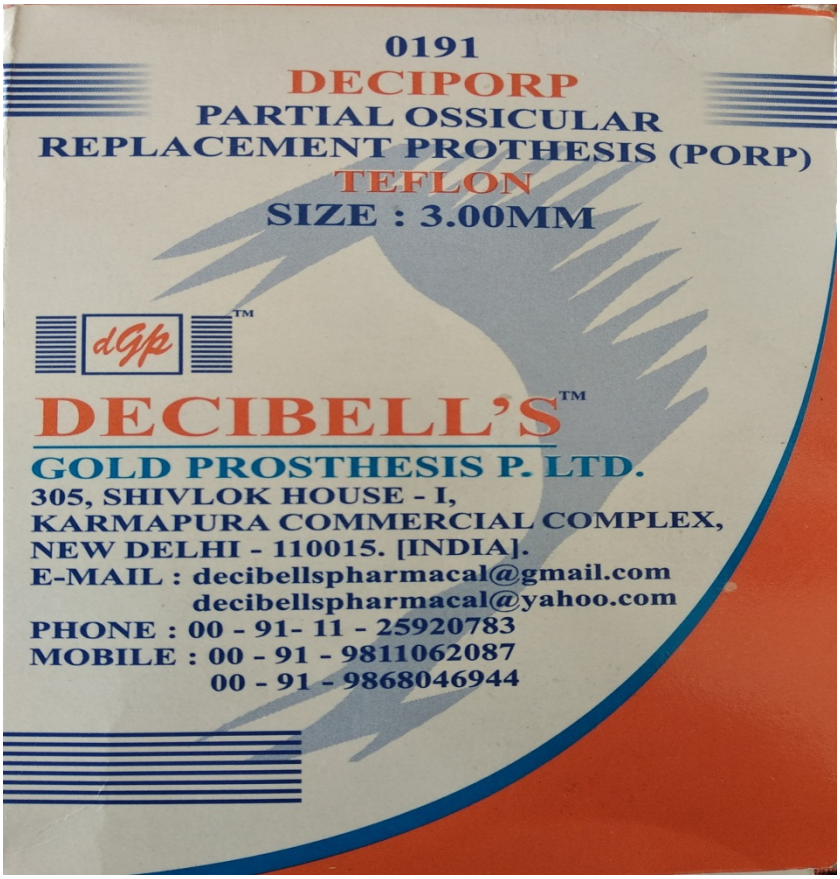


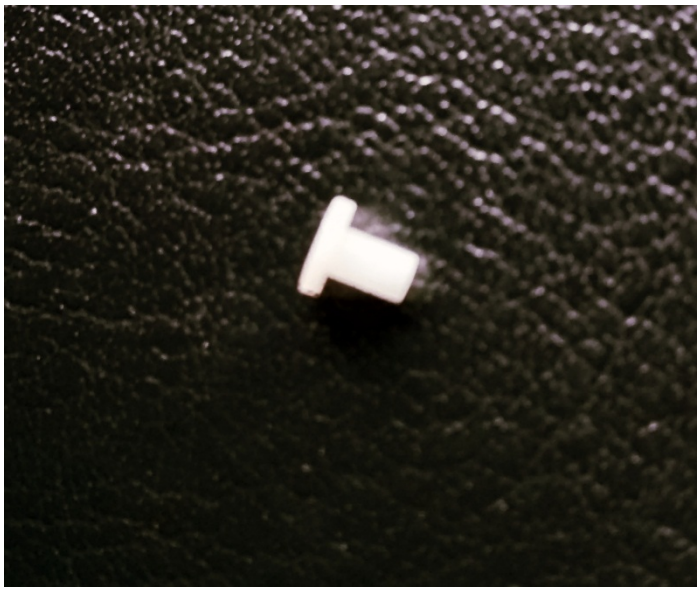
The cartilage is shaped with diamond burr with a facet for head of stapes. Graft placed over the head of stapes and a thin slice of cartilage placed over it. Gel foam kept all around the graft within the middle ear.

PORP OSSICULOPLASTY

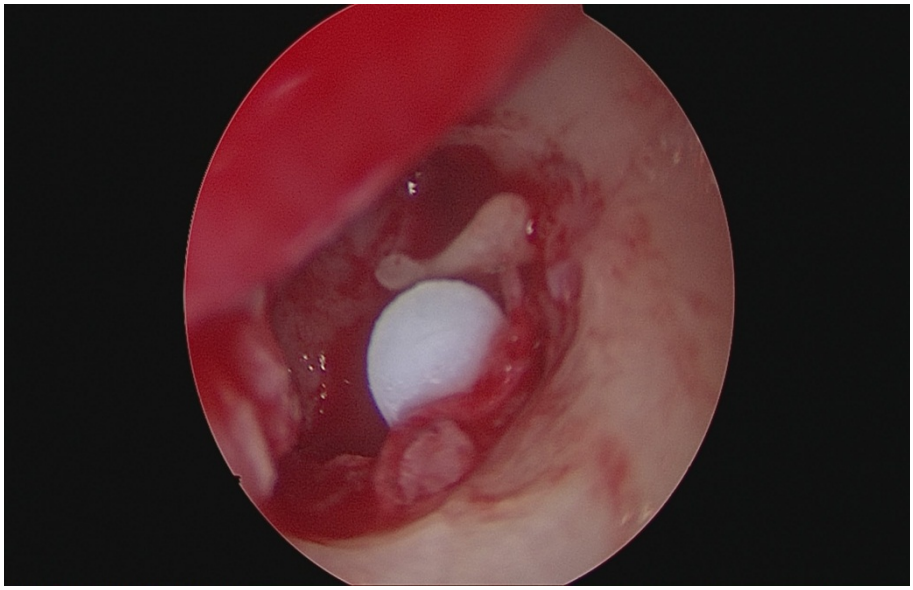
Partial ossicular replacement prosthesis done for the other half of patients.

The prosthesis which I used for ossiculoplasty is from Decibell's Partial Ossicular Replacement Prosthesis made of Teflon and of size 3mm

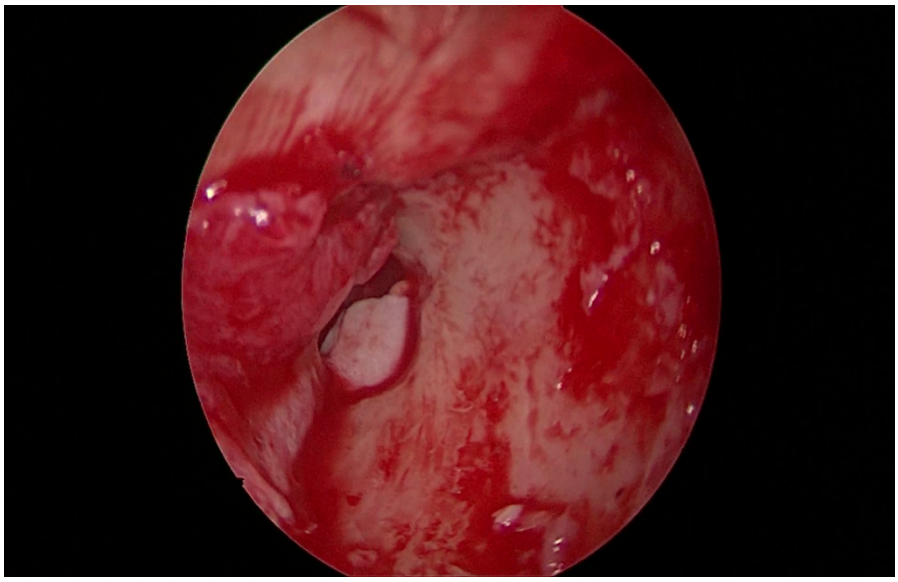

0191
DECIPORP
PARTIAL OSSICULAR
REPLACEMENT PROTHESIS (PORP)
TEFLON
SIZE : 3.00MM
dGp
DECIBELL'S
GOLD PROSTHESIS P. LTD.
305, SHIVLOK HOUSE - I,
KARMAPURA COMMERCIAL COMPLEX,
NEW DELHI - 110015. [INDIA].
E-MAIL : decibellspharmacal@gmail.com
decibellspharmacal@yahoo.com
PHONE : 00 - 91- 11 - 25920783
MOBILE : 00 - 91 - 9811062087
00 - 91 - 9868046944



Partial ossicular replacement prosthesis ossiculoplasty done for the other half of cases. The prosthesis is measured for distance between tympanic membrane and suprastructure of stapes and fitted on the head of stapes.



The ossiculoplasty is completed with a cartilage cap over the prosthesis as interface between prosthesis and tympanic membrane.



The harvested temporalis fascia graft shaped to the size appropriate for the perforation and placed medial to elevated drum remnant and to malleus handle over gelfoam bed. Tympanomeatal flap repositioned; ear wick placed in the external auditory canal. After achieving complete hemostasis, post auricular wound closure done in layers and mastoid dressing applied. Patient weaned from anaesthesia.

POST OPERATIVE COURSE :

Patients belonging to both the study groups were treated similarly post operatively with parenteral antibiotics for 7 days. Periodical dressing change done. Suture removal and ear wick removal done on the 8^{th} post operative day. They were discharged on the 9^{th} post operative day after ensuring that the post aural wound was healthy and there is no abnormal ear discharge . Patients were asked to keep the ear dry and given oral antibiotics for a week and topical antibiotic – steroid drops for 2 weeks.

ASSESSMENT OF RESULTS :

Patients were followed up with otoscopic examination every week for first one month and monthly for next 3 months. Graft take up was recorded in the 1^{st} month and also checked for abnormal ear discharge. At the end of 3^{rd} month tunning fork test done, subjective hearing improvement enquired and recorded . Otoendoscopic examination done to know about graft status. Pure tone audiogram done at the end of 3rd month and 12^{th} month. Pure tone average, air bone gap, hearing gain were assessed. The results were tabulated and analysed statistically and conclusions drawn

RESULTS AND OBSERVATIONS

During the period from January 2017 - September 2018, we selected 40 patients who attended ENT OPD at Coimbatore Medical College Hospital who were diagnosed to have chronic otitis media with ossicular erosion (incus bone erosion alone with intact malleus and stapes) as per inclusion criteria. We proceeded with cortical mastoidectomy with Cartilage ossiculoplasty in half cases selected and PORP ossiculoplasty in remaining 20 patients in a random fashion. Postoperatively patients were followed up regularly with otoscopic examination every week for first one month and monthly for next 3 months. Pure tone audiogram was done at 3rd month and 12th month. And also subjective improvement and graft uptake noted. Whole data compiled and statistical analysis done using statistical software.

AGE DISTRIBUTION IN BOTH GROUP

TABLE - 1

Age category	Cartilage Ossiculoplasty (Frequency)	Percentage	Porp ossiculoplasty (Frequency)	Percentage
15-30 years	8	40	9	45
31-40 years	7	35	6	30
> 40 years	5	25	5	25
Total	20	100.0	20	100.0

CHART - 1

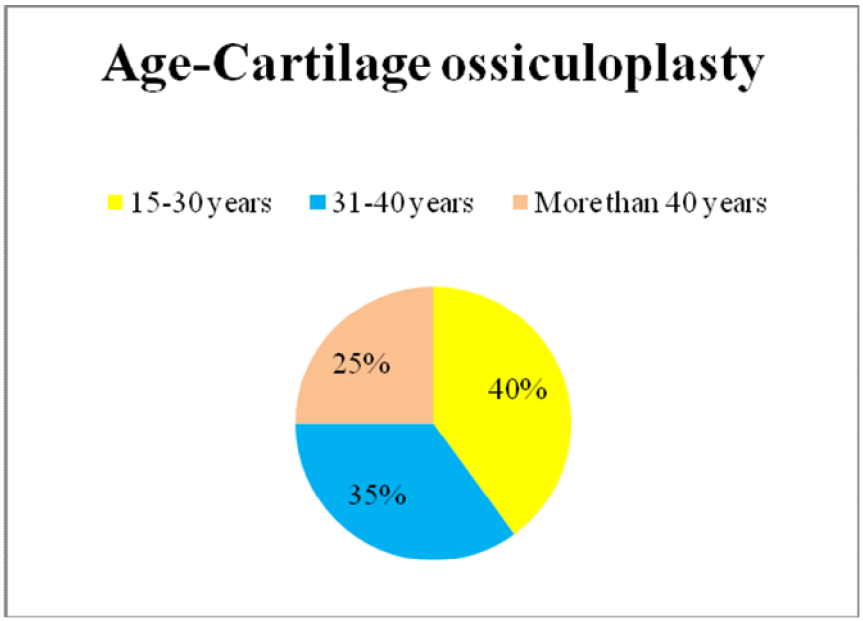
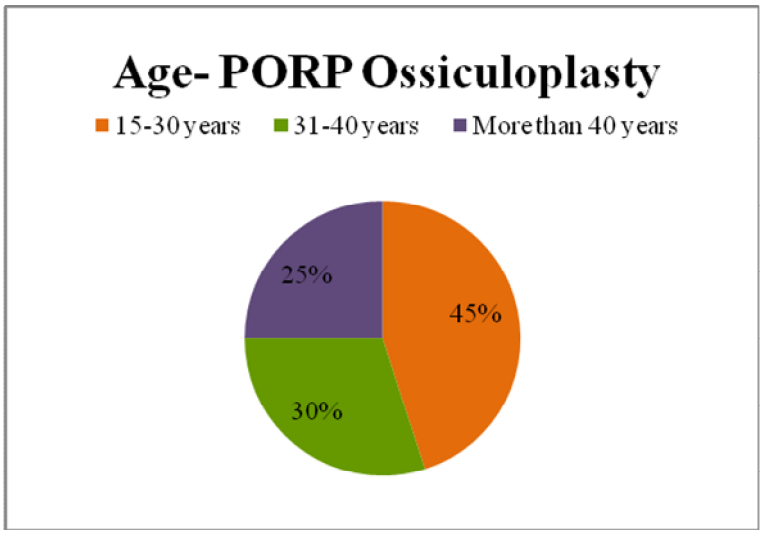


CHART - 2



Out of the 40 patients, those between 15-50, 17 were aged below 30 , 13 patients between 31 - 40 and 10 patients above the age of 40 .In both groups majority of cases who underwent surgery belongs to the age group 15-30 (40% in cartilage ossiculoplasty group and 43% in PORP ossiculoplasty group). 25% of both groups were above 40 years.

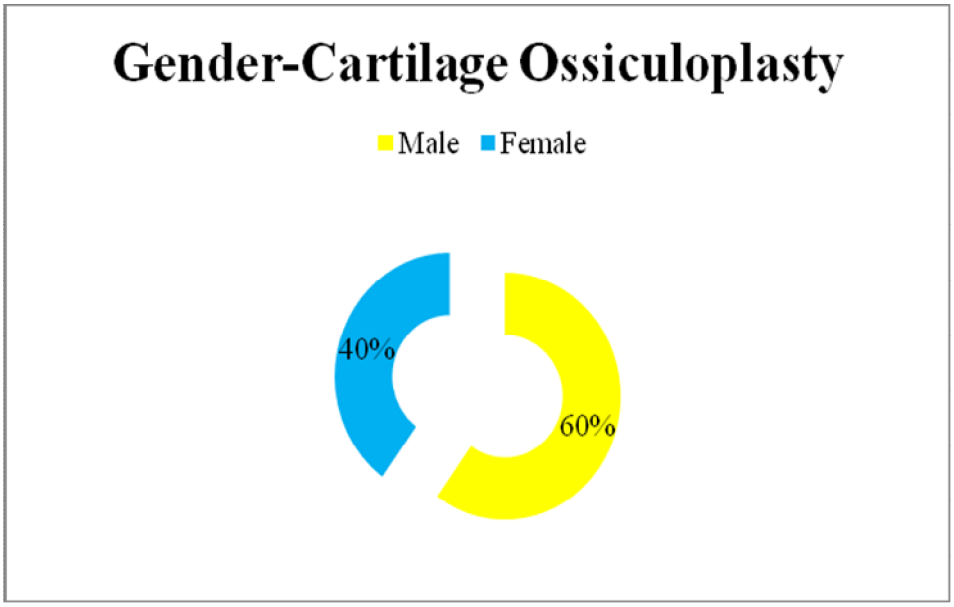
GENDER

CARTILAGE OSSICULOPLASTY

TABLE - 2

GENDER	FREQUENCY	PERCENTAGE
MALE	12	60
FEMALE	8	40
TOTAL	20	100.0

CHART - 3

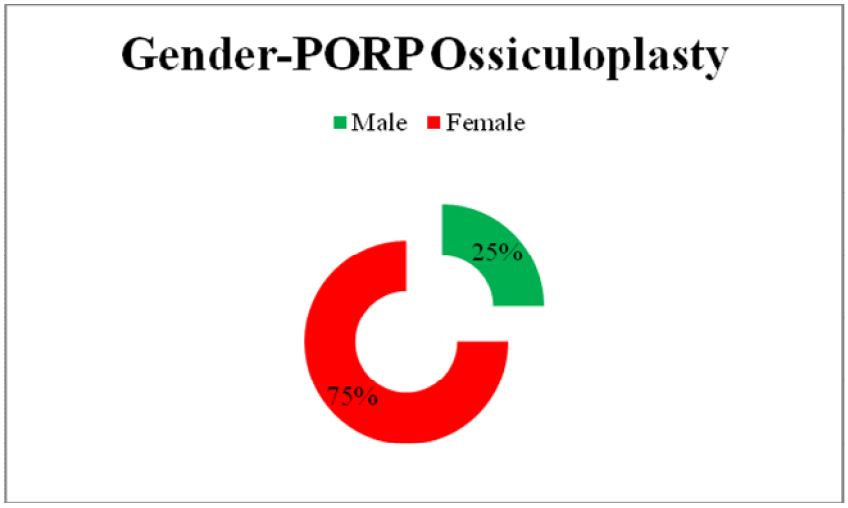


PORP OSSICULOPLASTY

TABLE - 3

GENDER	FREQUENCY	PERCENTAGE
MALE	5	25
FEMALE	15	75
TOTAL	20	100.0

CHART – 4



Among the patients operated, 60% of cases who underwent Cartilage ossiculoplasty were males, whereas 75% of cases who underwent PORP ossiculoplasty were females. As per study 57% of cases diagnosed with chronic otitis media with ossicular erosion and underwent ossiculoplasty were females.

COMPARISON OF AGE AND GENDER

TABLE - 4

Comparison of age & gender of study participants	Male Frequency	Female Frequency
15-30 years	6	11
31-40 years	4	9
More than 40 years	7	3
Total	17	23

Compiling both age and gender, it is clear that majority of cases belong to the age group 15 – 30 and 11% of them were females. Considering cases above the age of 40, 7% were males and only 3% constitutes females.

The ratio between females and males were found to be 1.3 : 1, which is correlating with the study done in 2013 at Uttarakhand State,India[41]. According to their study 53.92% cases with chronic otitis media were females and 46.08% of cases were males with a sex ratio(female:male) of 1.2 :1[42,43].

They also noticed that the mean age for peak incidence of chronic otitis media as 25.6 [44].

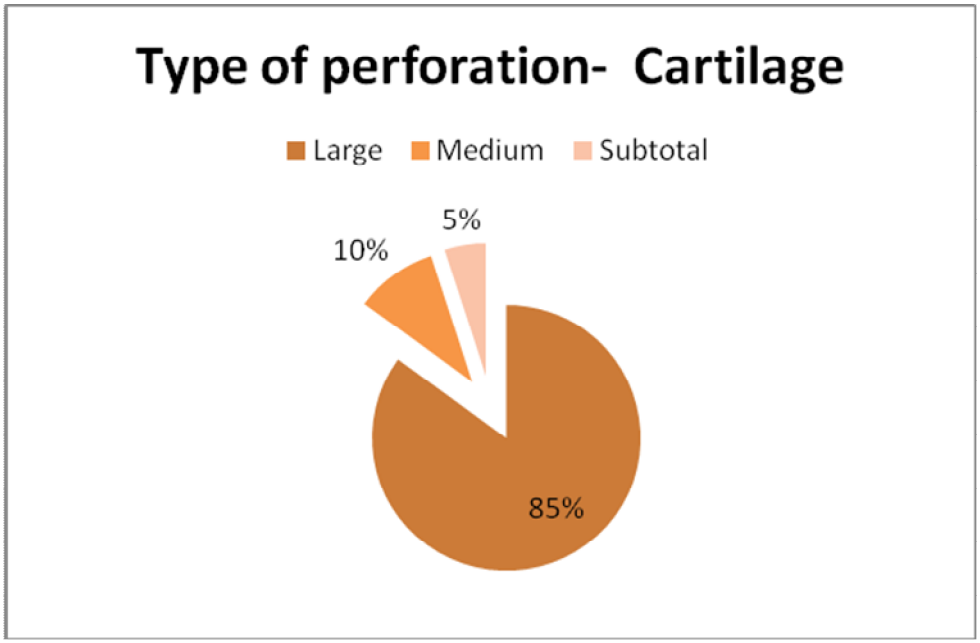
TYPE OF PERFORATION

CARTILAGE OSSICULOPLASTY

TABLE - 5

TYPE	FREQUENCY	PERCENTAGE
LARGE	17	85
MEDIUM	2	10
SUBTOTAL	1	5
TOTAL	20	100.0

CHART - 5



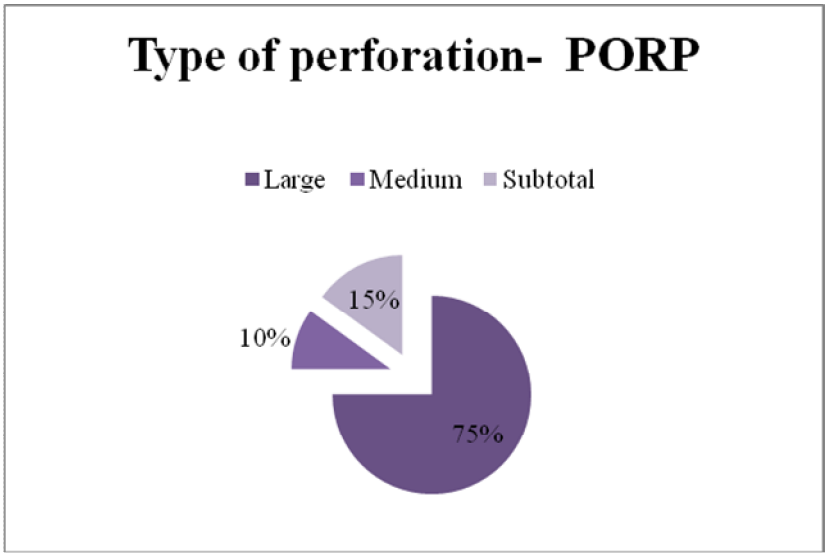
85% of cases who underwent cartilage ossiculoplasty were diagnosed with large central perforation pre operatively. 10 % cases had medium sized central perforation and only 5 % had subtotal perforation.

PORP OSSICULOPLASTY

TABLE - 6

TYPE	FREQUENCY	PERCENTAGE
LARGE	15	75
MEDIUM	2	10
SUBTOTAL	3	15
TOTAL	20	100.0

CHART - 6



75% of cases who underwent PORP ossiculoplasty, diagnosed with large central perforation pre operatively.10% cases had medium sized central perforation and 15 % had sub total perforation. None of the cases diagnosed with small central perforation. \

Among 40 patients selected for ossiculoplasty, 32 (80%) patients had large central perforation at presentation. Only 4 cases presented with subtotal perforation and 4 cases with medium sized central perforation.

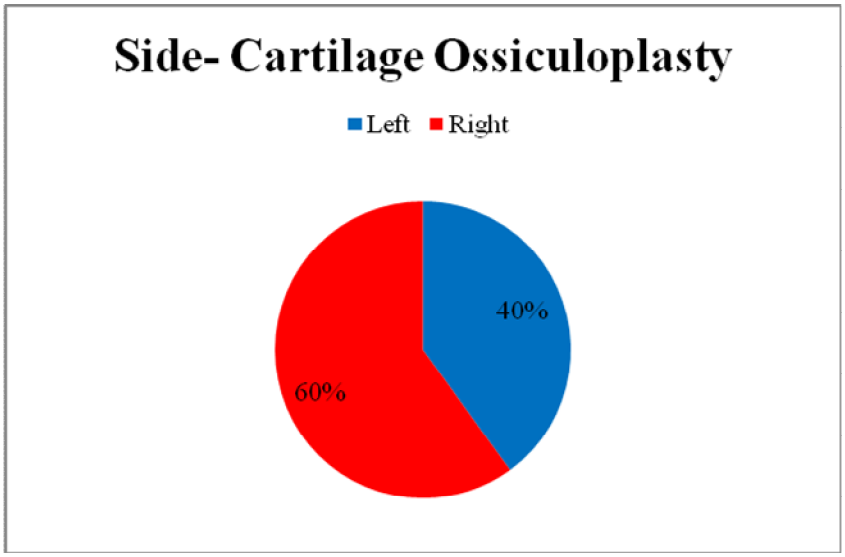
SIDE OF THE DISEASE

CARTILAGE OSSICULOPLASTY

TABLE - 7

SIDE	FREQUENCY	PERCENTAGE
LEFT	8	40
RIGHT	12	60
TOTAL	20	100.0

CHART - **7**



It is very obvious from the table and chart that out of 20,12 patients (60%) who underwent cartilage ossiculoplasty had right sided disease

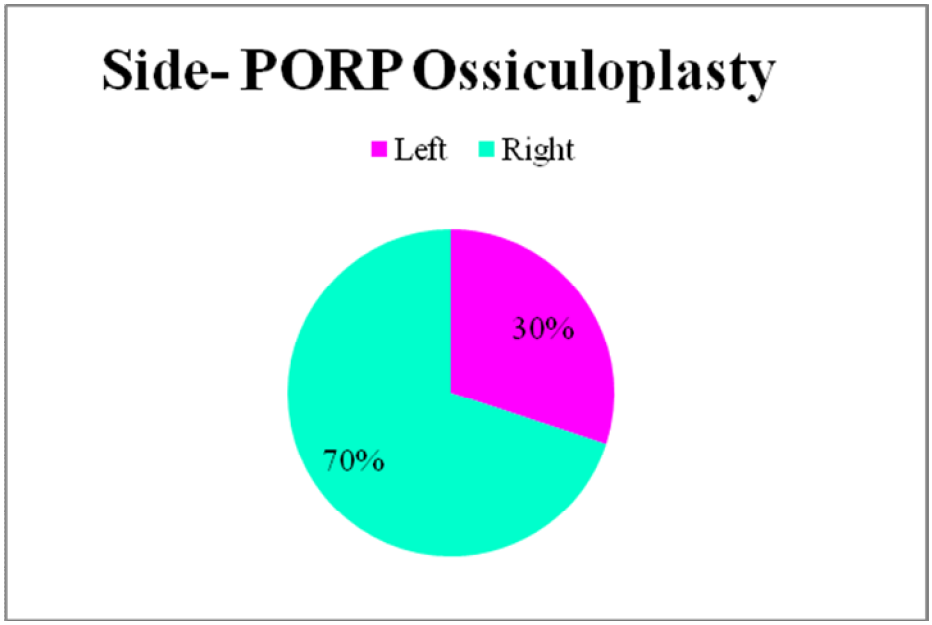
SIDE OF THE DISEASE

PORP OSSICULOPLASTY

TABLE - 8

SIDE	FREQUENCY	PERCENTAGE
LEFT	**6**	**30**
RIGHT	**14**	**70**
TOTAL	**20**	**100.0**

CHART-8



Out of 20 cases 14 cases had right sided disease which constitutes 70% of patients.

PREOPERATIVE PURE TONE AVERAGE

CARTILAGE OSSICULOPLASTY

TABLE – 9

PRE-OP PTA	FREQUENCY	PERCENTAGE	MEAN	SD
20-40	**0**	**0**	**43.91**	**12.45**
40-55	**6**	**30**		
>55	**14**	**70**		
TOTAL	**20**	**100**		

POST OPERATIVE PURE TONE AVERAGE

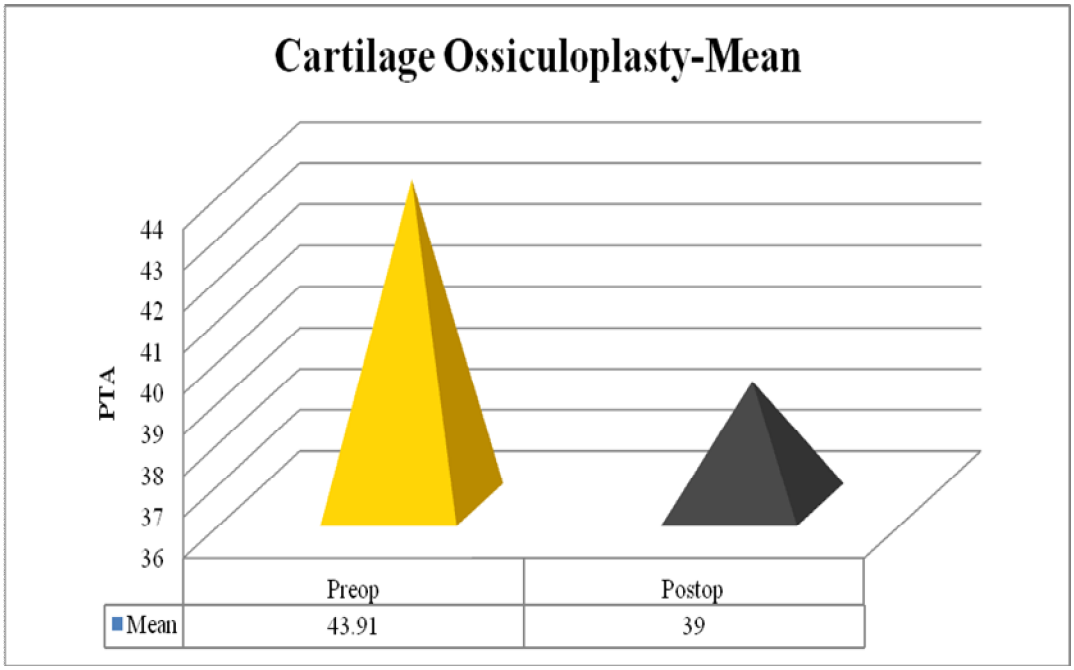
CARTILAGE OSSICULOPLASY

TABLE - 10

POST OP PTA	FREQUENCY	PERCENTAGE	MEAN	SD
40-55	13	65	39.00	7.63
> 55	7	35		
Total	20	100		

COMPARISON OF PRE- OP AND POST- OP PTA IN CARTILAGE OSSICULPLASTY

CHART - 9



From my study I found out that, there are no patients with pure tone average below 40dB preoperatively, which is a clear evidence of ossicular erosion. The mean pure tone average before cartilage ossiculoplasty was 43.91 (SD-12.45) which improved to mean pure tone average of 39 (SD-7.63) post operatively. There is hearing improvement of about 5 decibel postoperatively.

PRE OPERATIVE PURE TONE AVERAGE

PORP OSSICULOPLASTY

TABLE -11

PRE OP-PTA	Frequency	Percentage	Mean	SD
20-40	0	0	47.91	7.25
40-55	4	20		
> 55	16	80		
Total	20	100		

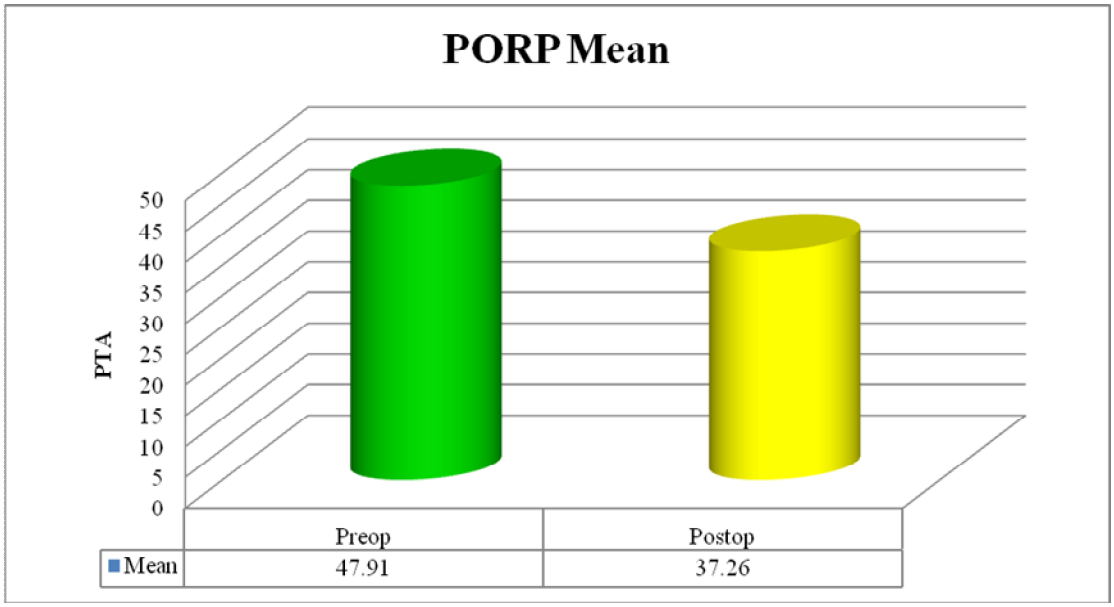
POST OPERATIVE PURE TONE AVERAGE

PORP OSSICULOPLASTY

TABLE - 12

Post op PTA	Frequency	Percentage	Mean	SD
20-40	0	0	37.26	7.51
40-55	16	80		
More than 55	4	20		
Total	20	100		

CHART - 10



80% patients who underwent PORP ossiculoplasty had a hearing loss of more than 55dB preoperatively. None presented with hearing below 40dB and 20% had hearing between 40 and 55dB. The mean pure tone average of 20 patients who underwent PORP ossiculoplasty were 47.91 (SD- 7.25) pre operatively, which improved to 37.26 (SD- 7.51) post operatively. Only 20% patients have PTA more than 55dB postoperatively.

PREOPERATIVE - AIR BONE GAP

CARTILAGE OSSICULOPLASTY

TABLE – 13

	Frequency	**Percentage**	**Mean**	**SD**
20-40	15	75	35.67	8.43
More than 40	5	25		
Total	20	100		

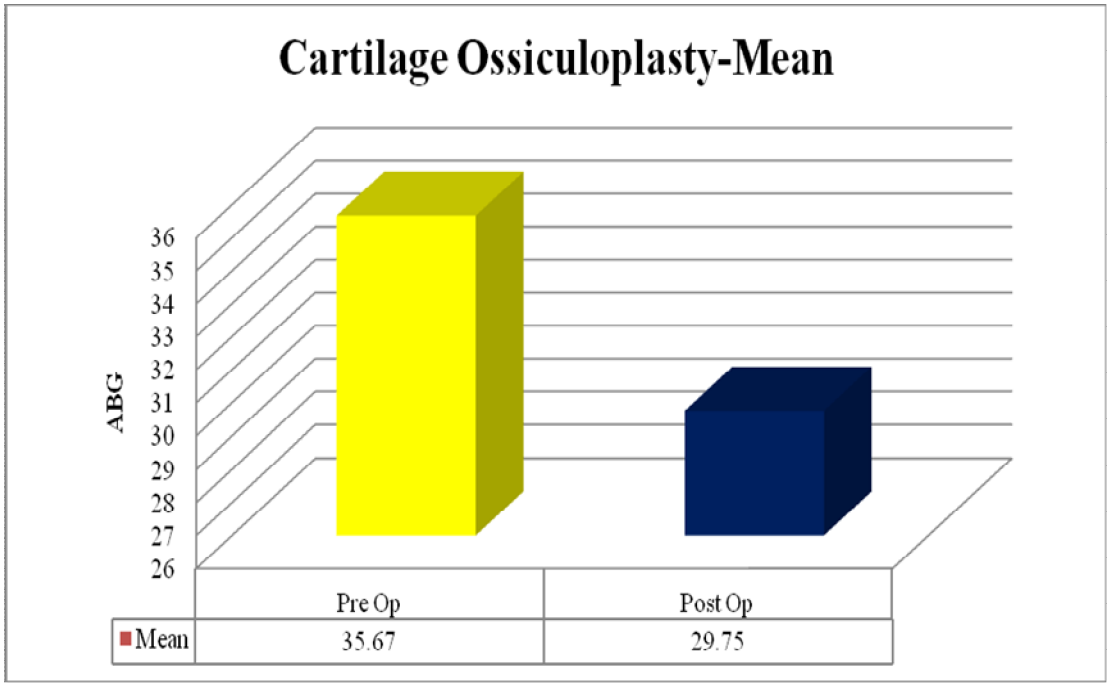
POST- OPERATIVE - AIR BONE GAP

CARTILAGE OSSICULOPLASTY

TABLE - 14

	Frequency	**Percentage**	**Mean**	**SD**
10-20	3	15	29.75	7.97
20-40	15	75		
More than 40	2	10		
Total	20	100		

CHART - 11



The mean preoperative air bone gap was 35.6% in preoperative period. Which got reduced to mean air bone gap of 29.75 postoperatively. This shows an obvious improvement in hearing.

TABLE – 15

Pre op – ABG	Frequency	Percentage	Mean	SD
20-40	11	55	40.20	7.06
> 40	9	45		
Total	20	100		

POST- OPERATIVE - AIR BONE GAP

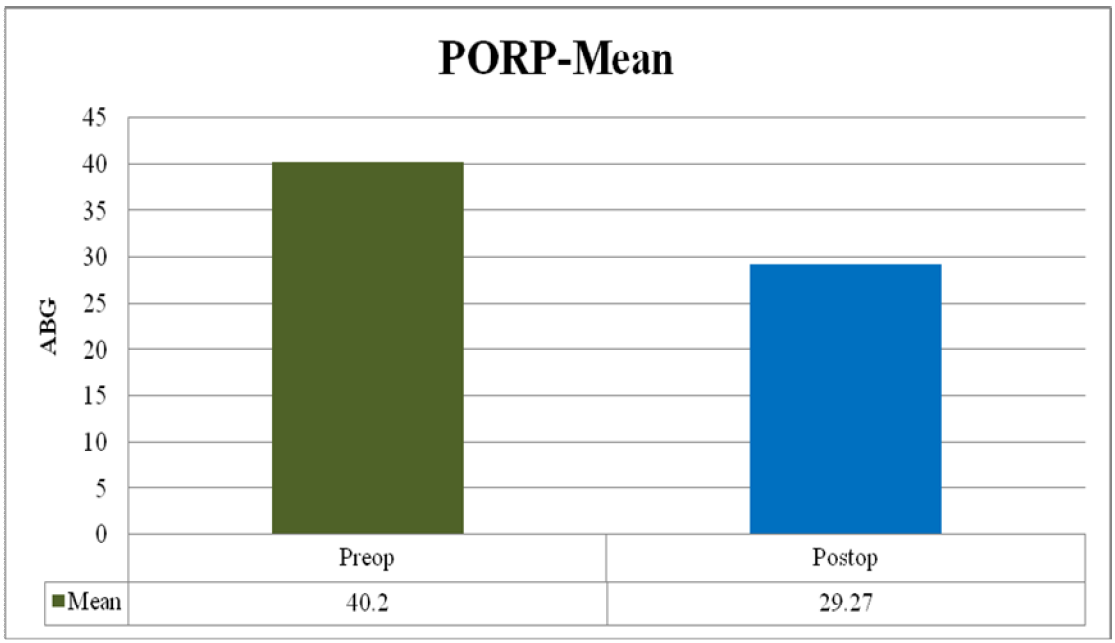
PORP OSSICULOPLASTY

TABLE – 16

	Frequency	Percentage	Mean	SD
10-20	3	15	29.27	8.92
20-40	16	80		
More than 40	1	5		
Total	20	100		

PORP OSSICULOPLASTY -ABG

CHART - 12



45% of patients of had air bone gap of more than 40dB and 55% cases had air bone gap less than 40 but more than 20 preoperatively. After surgery except one cases all other patients had an significant improvement.In 80% air bone gap came between 20-40dB and 15% cases drastically improved with ABG below 20dB.

INDEPENDENT T TEST

ABG REDUCTION

TABLE - 17

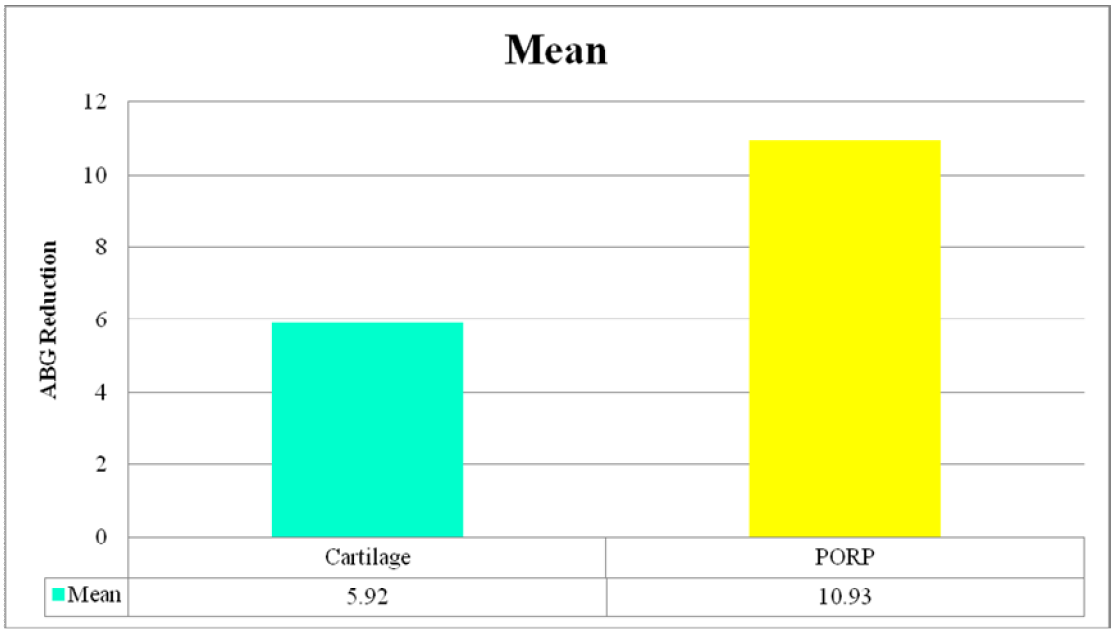
	Group	N	Mean	SD	P value
ABG Reduction	1	20	5.920	3.97	0.01
	2	20	10.930	4.97	

P value-0.01(p< 0.05 which is significant)

Group 1 – cartilage ossiculoplasty

Group 2 – Porp ossiculoplasty

CHART - 13



EXTRUSION

TABLE - 18

	Group	N	Mean	SD	P value
Extrusion	PORP	20	2.00	0.000	0.330
	CARTILAGE	20	1.95	0.224	

Out of 20 cases underwent PORP ossiculoplasty, 19 cases showed better results except one case who presented with PORP extrusion at 3rd month postoperatively. No other cases found to have extrusion in a one year follow up study. Statistically the p value found to be .330 which made it insignificant.

HEARING GAIN FOLLWING OSSICULOPLASTY

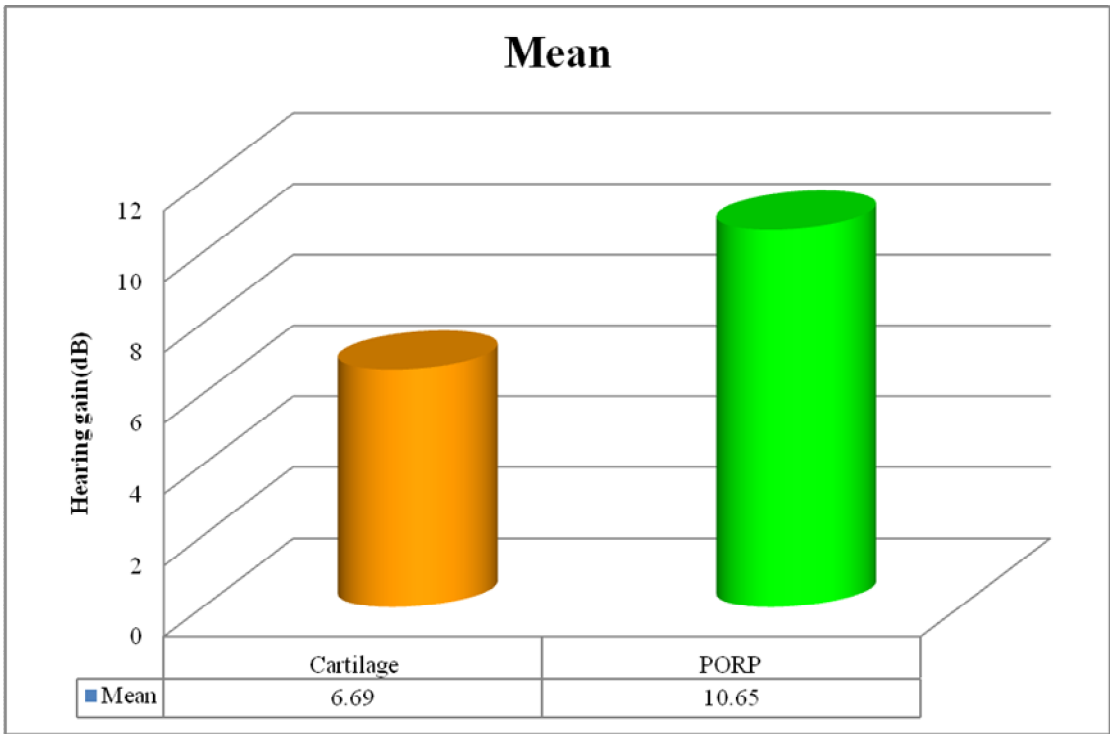
TABLE - 19

	Group	N	Mean	SD	P value
Hearing Gain(dB)	1	20	6.69	5.698	0.014
	2	20	10.65	3.698	

Group 1 – cartilage ossiculoplasty

Group 2 – Porp ossiculoplasty

CHART-14



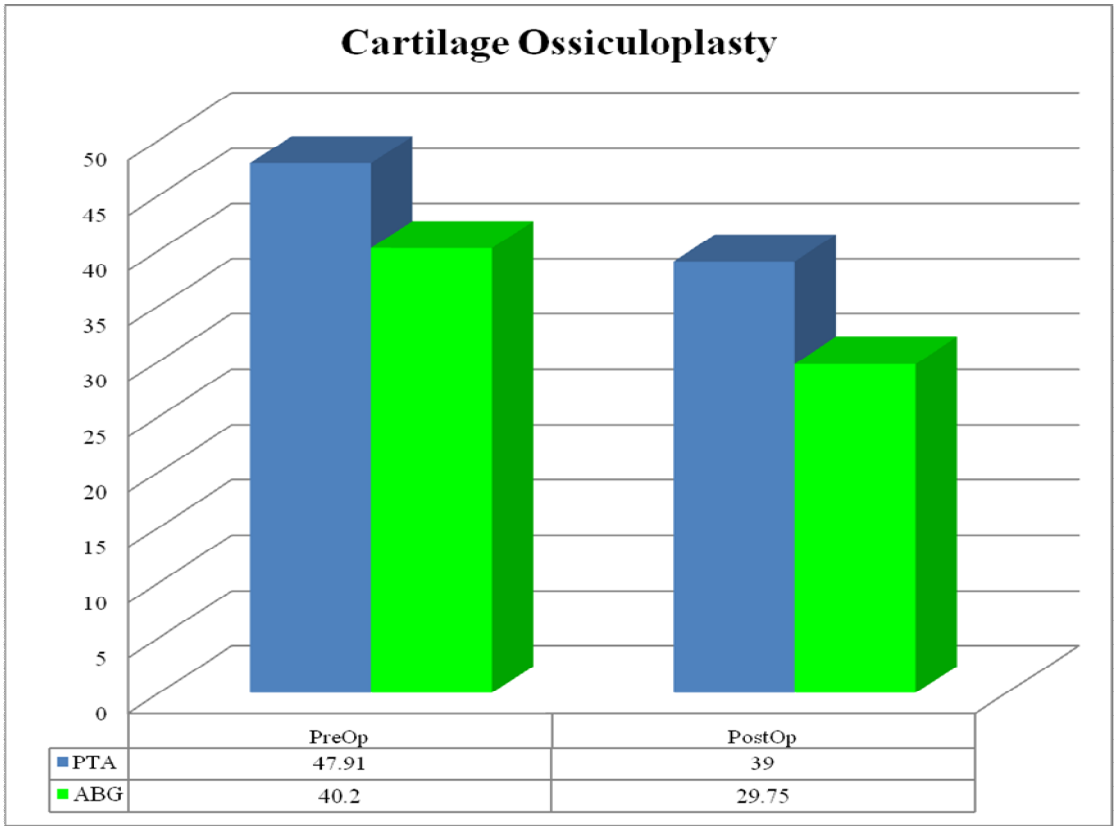
On comparing hearing gain following Cartilage and PORP ossiculoplasty, we found an improvement of 10.65Db (SD – 3.698) in patients undergone PORP ossiculoplasty.Following cartilage ossiculoplasty the mean hearing improvement was 6.69dB (SD – 5.698), the p value being 0.014 ,hence the hearing improvement after PORP ossiculoplasty found to be significant.

PAIRED T TEST

TABLE - 20

			Mean	SD	P Value
1	Pair 1	PTA pre op – PTA post op	4.90800	11.08370	0.062
	Pair 2	ABG pre op – ABG post op	5.92000	3.97328	0.001
2	Pair 1	PTA pre op – PTA post op	10.65500	3.69857	0.001
	Pair 2	ABG pre op – ABG post op	10.93000	4.97838	0.001

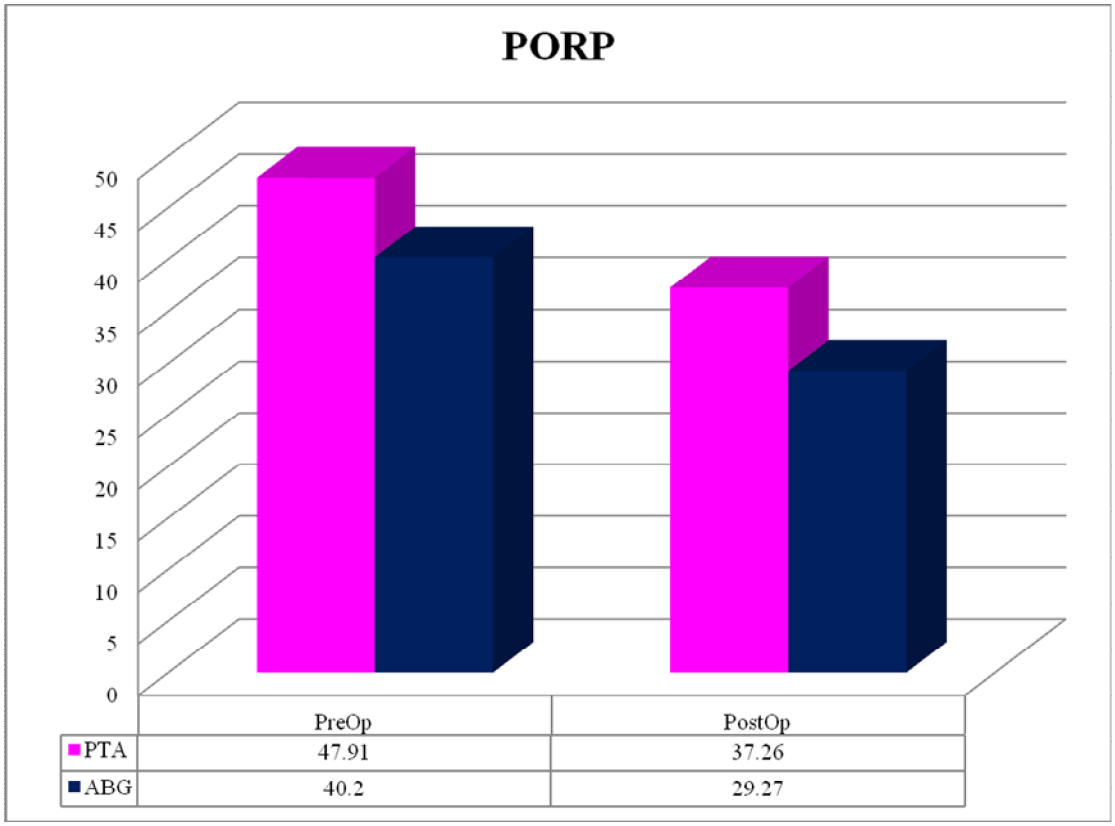
CHART - 15



This chart compares the pre operative mean pure tone average and mean air bone gap with mean pure tone average and ABG after cartilage ossiculoplasty. The mean pure tone average improved to 39dB from 47.91dB following surgery. Mean air bone gap also found to be dramatically improved following ossiculoplasty.

PORP OSSICULOPLASTY

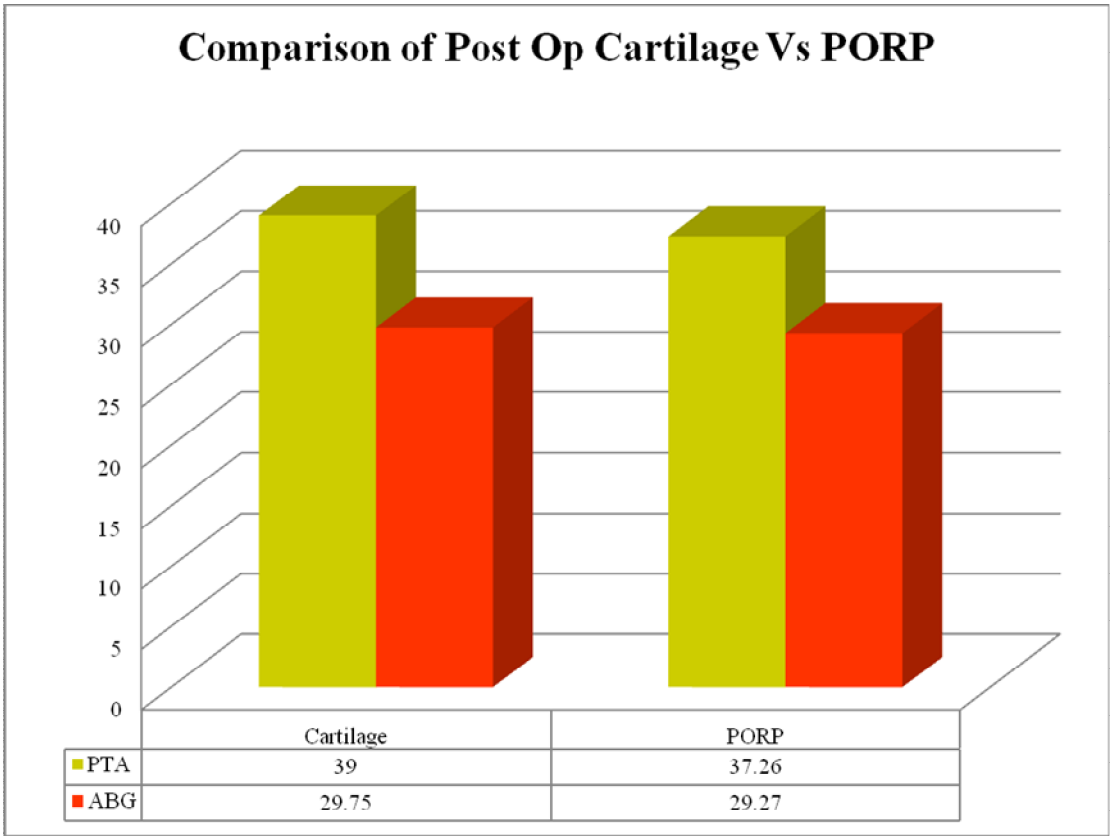
CHART-16



This chart analyses pre operative and post operative improvement in terms of mean pure tone average and mean air bone gap following PORP ossiculoplasty.

COMPARISON OF POST OPERATIVE RESULTS

CHART -17



This chart demonstrates the output in terms of hearing following Cartilage and PORP ossiculoplasty.

DISCUSSION

Over the years, numerous surgical modifications and refinements has been developed in the techniques of ossiculoplasty, which have been suggested by otologists from time to time with a view to further enhance its results.

This study is an attempt at evaluating the hearing improvement following ossicular reconstruction using autograft conchal cartilage and PORP.

In our study, patients with similar clinical presentations and diagnosed with chronic otitis media were randomly designated into two groups so that selection bias is avoided. Only patients with incus bone erosion which was confirmed by otoendoscopic examination, PTA, CT Temporal bone and intraoperatively were included and presence of paranasal sinus pathology was ruled out by diagnostic nasal endoscopy.

Incidentally, majority of our patients happened to be females(57.5%), reflecting the outpatient trends in our department. But gender difference has been shown not to affect the results of ossiculoplasty.

Patients from a wide age range 15 – 55 years were included. Extremes of age were avoided because of the possibility of existence of the coexistence of sensorineural loss in the elderly, comorbidities and underlying septic foci in children. Majority of the cases were below 30 years and those above 40 years

were only 10 in number. 80 % of cases had large central perforation with an average duration of 5.9 years with a SD of 4.01 and 65 % were right sided.

The overall ossiculoplasty success rate in our study was 92.5%. Ossiculoplasty doesnot found to affect the graft take up.

On comparision , the mean pre operative pure tone average found to be 43.9 in cartilage ossiculoplasty group and 47.91 in PORP ossiculoplasty cases. In cartilage ossiculoplasty group 70% cases had hearing loss more than 55dB and 30% cases had hearing loss more than 40dB at the of presentation.

In PORP group 80% cases had hearing loss of more than 55dB and 20% above 40dB pre operatively.

Audiogram was done 3 months and 12 months postoperatively and mean PTA was 39 and 37.26 for cartilage and PORP ossiculoplasties respectively with a hearing gain of 6.69 (mean PTA, SD-5.69) for cartilage ossiculoplasty and 10.65(mean PTA) with SD of 3.69 for PORP ossiculoplasty making the result statistically significant.

80% cases of PORP ossiculoplasty had an significant improvement following PORP ossiculoplasty whereas 65% cases improved dramatically following cartilage ossiculoplasty.

On observing the patients' responses regarding subjective status of hearing during the third month, a significanty proportion of study group

patients reported as having good/fair improvement when compared to controls. This fact is of practical importance in day to day routine even though not documented audiologically.

The mean air bone gap observed prior to surgery was 36.67 and 40.20 in cartilage and PORP groups, which reduced to 29.75 and 29.27 postoperatively resulting in air bone reduction of about 5.92 (mean) in cases underwent cartilage ossiculoplasty and 10.93 (mean) for those with PORP giving a p value of 0.01, hence the result found to be significant.

Even though extrusions are common with prosthesis ossiculoplasties as per literature, in this study only 1 extrusion case was reported among 20 cases done in a time period of 1 year postoperatively. The p value is .330, hence insignificant.

SUMMARY

This was an experimental randomized control study involving 40 patients who attended the outpatient department of Coimbatore Medical College Hospital and diagnosed with tubotympanic type of CSOM with ossicular erosion. They were designated into two groups with regard to the type of ossiculoplasty. Out of 40 patients half cases underwent cartilage ossiculoplasty and remaining 20 cases underwent PORP ossiculoplasty. Patients were under regular follow up and the following trends were noted.

The mean pre operative pure tone average of both the groups found to be 43.9 in cartilage ossiculoplasty group and 47.91 in PORP ossiculoplasty group. Patients were followed up regularly and in repeated pure tone audiogram taken, mean PTA was 39 for cartilage ossiculoplasty and found to be 37.26 for PORP ossiculoplasties. Comparing both there was a hearing gain of 6.69 (mean PTA, SD -5.69) for cartilage ossiculoplasty and 10.65 (mean PTA, SD -3.69) for PORP ossiculoplasty making the result statistically significant.

Subjective post operative hearing was better in patients who underwent PORP ossiculoplasty when compared cartilage ossiculoplasty group (65% of PORP cases reported that their post operative hearing was ‘good’ compared to 40% of cartilage ossiculoplasty cases.)

With regard to air bone gap reduction, the mean air bone gap found to be reduced from 36.67 to 29.75 following surgery in cases with cartilage ossiculoplasty and mean air bone gap 40.20 dropped to 29.27 in PORP ossiculoplasty cases. On an average air bone reduction is about 5.92 (mean) in cases underwent cartilage ossiculoplasty and 10.93 (mean) for those with PORP giving a p value of 0.01, hence the result found to be significant.

Even though extrusions are common with prosthesis ossiculoplasties as per literature, in this study only 1 extrusion case was reported among 20 cases done in a time period of 1 year postoperatively. The p value is .330, hence insignificant.

CONCLUSION

From the study, it is evident that PORP ossiculoplasty is more beneficial compared to autograft conchal cartilage regarding hearing restoration.

Even though it doesnot significantly alter the extent of air bone gap closure at 3 months post operatively, an extended period of follow up is needed to estimate the ultimate audiological outcome. A limitation of this study is that the period of follow up is inadequate to assess whether grft gets extruded which might reverse the beneficial effects.

With the available evidence , this procedure is worth trying in cases with chronic otitis media with definite incus bone erosion and intact stapes suprastructure, as this simple prosthesis found to significantly modify the surgical outcome in a benificial manner to a considerable extent. Further studies are needed to quantify its surgical implications in the long run before it can be incorporated routinely in a standardized manner.

1. Ossiculoplasty definitely gives better hearing results in cases of chronic otitis media with ossicular erosion, when compared to cases who don't underwent ossiculoplasty.

2. Ossiculoplasty should be done in all cases with conductive hearing loss due to ossicular erosion

3. It can be done either in primary sitting or second sitting.

4. Comparing autograft cartilage and PORP graft, PORP ossiculoplasties have a better postoperative hearing, in terms of hearing gain and air bone reduction.

5. PORP is biocompatible, stable, safe, affordable and easily available.

6. Complications in the short period studied are nil in both groups.

7. Both Cartilage and PORP are taken up well in the three month followup.

8. Long term results are awaited.

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PROFORMA

NAME :

AGE :

SEX :

IP NUMBER :

COMPLAINTS

Ear discharge

Hard of hearing

Ear pain

Tinnitus / vertigo

Nasal symptoms

HISTORY OF PRESENTING ILLNESS :

- EAR DISCHARGE
- duration
- quantity
- colour
- whether foul smelling/ blood stained
- duration for which ear is dry
- HARD OF HEARING
- degree of hard of hearing
- onset

- progression
- TINNITUS : present / absent
- VERTIGO : present / absent
- OTALGIA
- NASAL SYMPTOMS :
- obstruction
- discharge

PAST HISTORY :

Systemic diseases – diabetes ,hypertension, tuberculosis

History of trauma

Noise exposure

Previous ear surgery / nasal surgery

Ototoxic drugs

PERSONAL HISTORY :

Occupation

Socioeconomic status

Smoking

EXAMINATION

- GENERAL EXAMINATION :
- VITAL SIGNS : pulse , temperature ,blood pressure
- SYSTEMS :

CVS

RS

CNS

ABDOMEN

OTOLOGICAL EXAMINATION:

RIGHT

LEFT

PRE AURICULAR REGION

PINNA

POST AURICULAR REGION

EXTERNAL AUDITORY CANAL

TYMPANIC MEMBRANE

PARS TENSA :

Perforation

Site

Size

Condition of middle ear mucosa

Any obvious ossicular erosion

If membrane intact :

-Lustre

-Cone of light: absent/ present/distorted

-Mobility

PARS FLACCIDA

3 FINGER TENDERNESS

FACIAL NERVE

FISTULA TEST

TUNING FORK TESTS

RINNE

WEBER

ABSOLUTE BONE CONDUCTION

NASAL CAVITY :

Anterior rhinoscopy

Post nasal examination

Para nasal sinus tenderness

ORAL CAVITY AND OROPHARYNX

INVESTIGATIONS

- Pure tone audiogram :
    - type of loss
    - pre operative hearing loss
    - pre operative air bone gap
- Xray mastoids
- Diagnostic nasal endoscopy
- CT Temporal bone

Others :

Blood counts, blood sugar, urea, chest Xray, ECG, urine examination

PER OPERATIVELY :

Side of operaterd ear

Anaesthesia

Ossicular status

Type of ossiculoplasty done

POST OPERATIVELY :

Facial nerve function

Giddiness / vomiting

1 st P.O.D : Post auricular wound

6th P.O.D : Post auricular wound

:Any abnormal ear discharge

1st week review : Post auricular wound

:Any abnormal ear discharge

:Graft status – taken up or not

1st month review : Graft status – taken up or not

3 rd month review -Graft status

- Subjective hearing impairment

-Tuning fork tests

- Otoscopy

- Post operative audiogram: Post operative hearing and air bone gap

12th month review

- Graft status
- Subjective hearing impairment
- Tuning fork tests
- Otoscopy
- Post operative audiogram: Post operative hearing and air bone gap

CONSENT FORM

Yourself, Mr./Mrs./Ms…….. are being asked to be a participant in the research study titled **“** A COMPARATIVE ANALYSIS OF HEARING IN CARTILAGE OSSICULOPLASTY AND PARTIAL OSSICULAR REPLACEMENT PROSTHESIS OSSICULOPLASTY**”** in Coimbatore Medical College Hospital, Coimbatore, conducted by Dr. VINEETHA.K , Post Graduate student, Department of ENT, Coimbatore Medical College. You are eligible after looking into the inclusion criteria. You may ask any question you may have before agreeing to participate.

Research being done

Prospective comparative study of hearing in cartilage ossiculoplasty and partial ossicular replacement prosthesis ossiculoplasty.

Purpose of research

1. Primary objective- To compare hearing outcome following autologous cartilage ossiculoplasty and PORP ossuiculoplasty in patients with chronic otitis media.

2. Secondary objective- To compare the ease of surgery, post-operative hearing gain, air bone gap reduction, graft extrusion and complications.

Procedures involved

40 patients admitted in ENT Department of Coimbatore Medical College Hospital, who are >15 years and <50 years, with chronic otitis media with incus bone erosion were selected. 20 of them underwent cartilage ossiculoplasty and other half underwent PORP ossiculoplasty.

Decline from participation

You have the option to decline from participation in the study.

Privacy and Confidentiality

Privacy of individuals will be respected. Any information, about you or provided by you, during the study will be kept strictly confidential.

Authorization to publish results

Results of the study may be published for scientific purposes and/or presented to scientific groups, however, you will not be identified.

Statement of consent

I volunteer and consent to participate in this study. I have read the consent / the consent has been read to me. The study has been fully explained to me and I may ask questions at any time pertaining to the same.

…….. …….

.

Signature/ Left thumb impression Date

(volunteer)

…….. ……..

Signature of witness Date

KEY TO MASTER CHART

ABG	AIR BONE GAP
CP	CENTAL PERFORATION
dB	DECIBEL
F	FEMALE
L	LEFT
M	MALE
PTA	PURE TONE AVERAGE
R	RIGHT

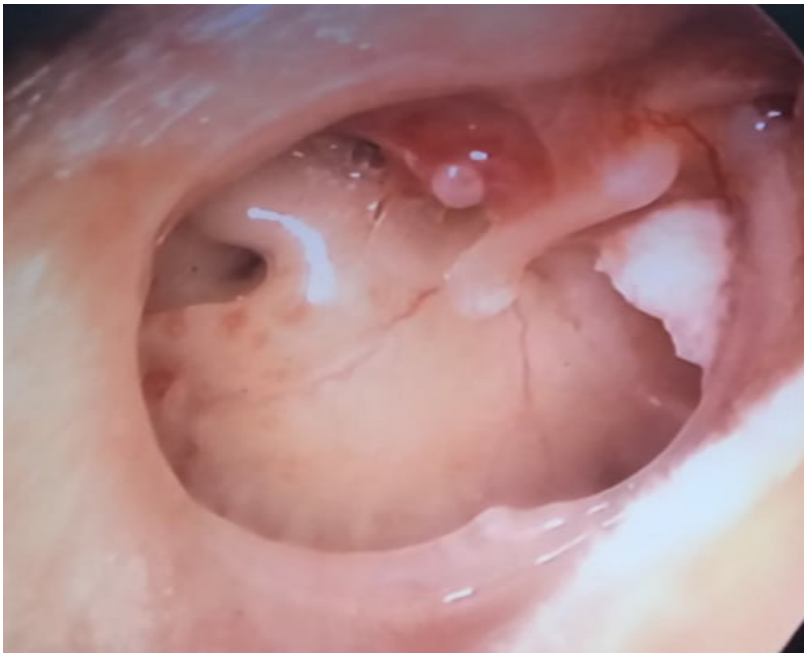
MASTER CHART

SL .NO	NAME	AGE/ SEX	TYPE OF PERFORATION	SIDE OF DISEASE	DURATION OF DISEASE	PTA (PRE OP)	ABG PRE OP	PTA (POST OP AT 12 MNTHS)	ABG (POST OP AT 12 MNTHS)	HEARING GAIN (dB)	ABG REDUCTION (dB)	EXTRUSION
1	ASFAQ SULTHAN	16/M	LARGE CP	R	5 YEARS	53.36 dB	43.3 dB	40 dB	33.3 dB	13.3	10	ABSENT
2	RUBINE	18/F	LARGE CP	R	10 YEARS	46.6 dB	35 dB	35 dB	28.6 dB	11.6	6.4	ABSENT
3	GEETHA	36/F	LARGE CP	L	8 MONTHS	35 dB	23.3 dB	28.3 dB	18.3 dB	6.7	5	ABSENT
4	JAYA SURYA	39/F	MEDIUM CP	R	6 MONTHS	35 dB	26.6 dB	25 dB dB	14.3 dB	10	12.3	ABSENT
5	BARATHAN	48/M	LARGE CP	R	1 YEAR	40 dB	33.6 dB	31.6 dB	28.3 dB	8.4	5.3	ABSENT
6	JOHNSON MICHAEL	45/M	LARGE CP	R	2 YEARS	43.6 dB	28.6 dB	33.3 dB	21.3 dB	10	7.3	ABSENT
7	NALLATHAMBI	21/M	SUBTOTAL CP	L	10 YEARS	43.3 dB	35 dB	38.6 dB	33.3 dB	4.7	1.7	ABSENT
8	ANANDHA KUMAR	27/M	MEDIUM CP	L	8 YEARS	45 dB	33.3 dB	46.6 dB	33.3 dB	(-)1.6	0	ABSENT
9	GOVINDARAJ	50/M	LARGE CP	R	3 YEARS	43.3 dB	28.3 dB	35 dB	26.6dB	8.3	1.7	ABSENT
10	PRAVEENA	35/F	LARGE CP	L	10 YEARS	38.3 dB	25 dB	48.3 dB	28.3 dB	(-)10	(-)3.3	ABSENT
11	YOGESWARI	27/F	LARGE CP	R	10 YEARS	43.3 dB	38.6 dB	36.6 dB	31.1 dB	6.7	7.5	ABSENT
12	RENUKA	40/F	LARGE CP	R	5 YEARS	36.6 dB	23.3 dB	31.6 dB	15 dB	5	8.3	ABSENT
13	RIZWANA	38/F	LARGE CP	R	4 YEARS	48 dB	40 dB	35 dB	31.3 dB	13	8.7	ABSENT
14	KUPPUSAMY	41/M	LARGE CP	L	10 YEARS	65 dB	45 dB	55 dB	38.6 dB	10	6.4	ABSENT
15	KARTHICK	27/M	LARGE CP	L	1 YEAR	48.3 dB	36 dB	41.6 dB	28.3 dB	6.7	7.7	ABSENT
16	MURUGAN	46/M	LARGE CP	L	14 YEARS	55 dB	46.6 dB	45 dB	38.6 dB	10	8	ABSENT
17	ANANDHAN	30/M	LARGE CP	R	5 YEARS	63.3 dB	55 dB	50 dB	43.6 dB	13.3	11.4	ABSENT
18	JAHIR HUSSAIN	33/M	LARGE CP	L	2 YEARS	40 dB	35 dB	40 dB	31.3 dB	0	3.7	ABSENT
19	SARAVANAN	31/M	LARGE CP	R	7 YEARS	48 dB	43.3 dB	45 dB	41.6 dB	3	1.7	ABSENT
20	KALAISELVI	27/F	LARGE CP	R	10 YEARS	43.3 dB	38.6 dB	38.6 dB	30 dB	4.7	8.6	ABSENT

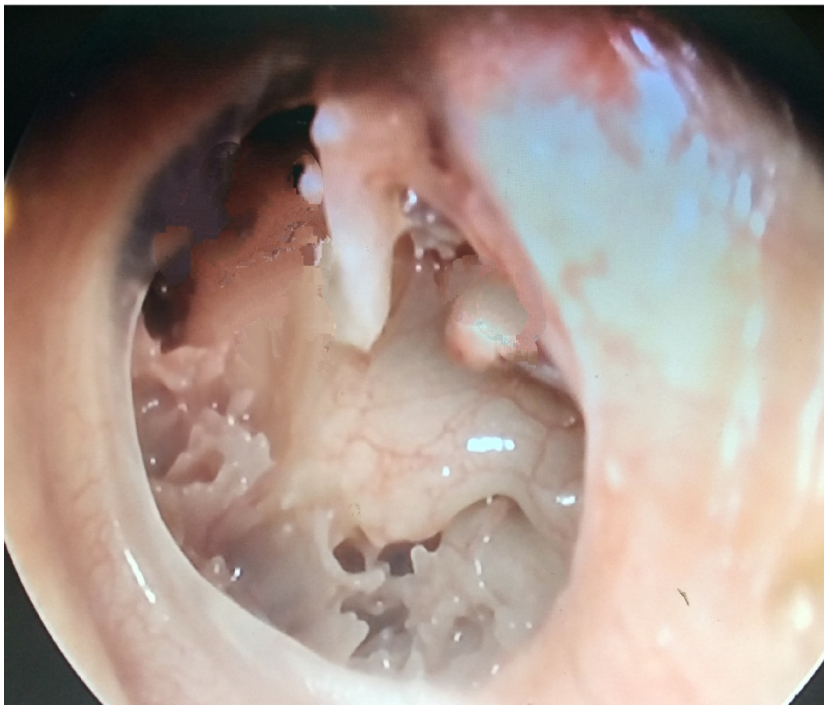
SL .NO	NAME	AGE/ SEX	TYPE OF PERFORATION	SIDE OF DISEASE	DURATION OF DISEASE	PTA (PRE OP)	ABG PRE OP	PTA (POST OP AT 12 MNTHS)	ABG (POST OP AT 12 MNTHS)	HEARING GAIN (dB)	ABG REDUCTION (dB)	EXTRUSION
1	SIVAKUMAR	34/M	LARGE CP	R	7 YEARS	48.6	43.3	33.6	30	15	13.3	ABSENT
2	SASIKALA	31/F	LARGE CP	R	3 YEARS	51.6	36.6	40	16.6	11.6	20	ABSENT
3	BAKIYALAKSHMI	27/F	LARGE CP	L	10 YEARS	53.3	36.6	40	25	13.3	11.6	ABSENT
4	JAYAPRIYA	21/F	LARGE CP	R	1YEAR	38.6	35	31.6	28.6	7	6.4	ABSENT
5	PRAVEENA	25/F	LARGE CP	R	10 YEARS	46.6	30	36.6	16.6	10	13.4	ABSENT
6	VALARMATHI	18/F	LARGE CP	L	10 YEARS	55	48.3	45	38.6	10	9.7	ABSENT
7	RAMESH	43/M	LARGE CP	R	5 YEARS	58.3	50	55	53.3	3.3	(-)3.3	PRESENT
8	RINGU DEVI	28/F	LARGE CP	R	5 YEARS	50	33.3	33.3	18.3	16.7	15	ABSENT
9	VELLINGIRI	29/M	SUB TOTAL CP	L	15 YEARS	35	33.6	28.3	25	6.7	8.6	ABSENT
10	MURUGAN	37/M	SUB TOTAL CP	R	10 YEARS	38.6	30	30	23.3	8.6	6.7	ABSENT
11	DHANASEKAR	42/M	LARGE CP	R	12 YEARS	48.3	45	33.3	28.6	15	16.4	ABSENT
12	GIRIJA	47/F	LARGE CP	L	2 YEARS	48.3	43.3	40	35	8.3	8.3	ABSENT
13	BANNARI	55/F	LARGE CP	R	3 YEARS	45	38.6	40	30	5	8.6	ABSENT
14	CHITHRA	32/F	MEDIUM CP	R	6 MONTHS	55	48.3	40	35	15	13.3	ABSENT
15	DAISY RANI	28/F	MEDIUM CP	R	4 YEARS	56.3	45	48.6	38.3	7.7	6.7	ABSENT
16	THENMOZHI	40/F	SUB TOTAL CP	L	1 YEAR	60	55	48.3	40	11.7	15	ABSENT
17	PRIYA	27/F	LARGE CP	R	7 YEARS	41.6	35	30	23.3	11.6	11.7	ABSENT
18	MARTHANDAL	48/F	LARGE CP	L	7 YEARS	41.3	40	30	25	11.3	15	ABSENT
19	THANGAMANI	30/F	LARGE CP	R	5 YEARS	48.6	43.6	33.3	30	15.3	13.6	ABSENT
20	KAVITHA	39/F	LARGE CP	R	2 YEARS	38.3	33.6	28.3	25	1O	8.6	ABSENT

COLOUR PLATES

SUBTOTAL PERFORATION WITH INCUS BONE ERSION

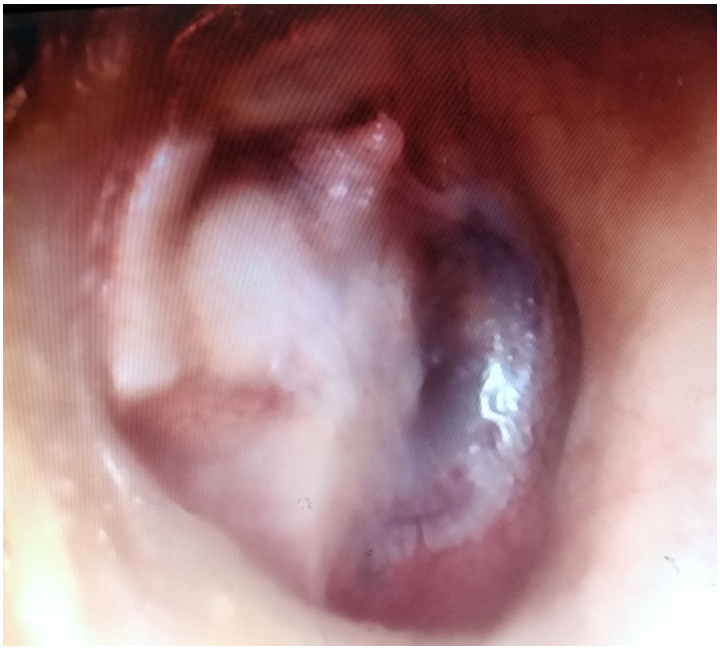


LARGE CENTRAL PERFORATION WITH INCUS BONE EROSION



POST OPERATIVE OTOENDOSCOPIC IMAGE OF PORP

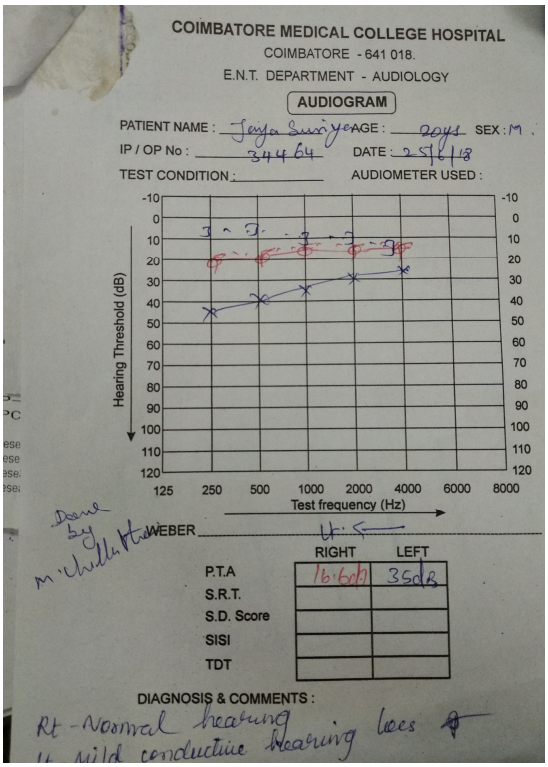
OSSICULOPLASTY



POST OPERATIVE OTOENDOSCOPIC IMAGE OF CARTILAGE

OSSICULOPLASTY

PRE OPRATIVE PURE TONE AUDIOGRAM



COIMBATORE MEDICAL COLLEGE HOSPITAL
COIMBATORE - 641 018.
E.N.T. DEPARTMENT - AUDIOLOGY

AUDIOGRAM

PATIENT NAME : Jenja Suriya AGE : 20yrs SEX : M
IP / OP No : 34464 DATE : 25/6/18
TEST CONDITION : AUDIOMETER USED :

Hearing Threshold (dB)
-10 0 10 20 30 40 50 60 70 80 90 100 110 120
125 250 500 1000 2000 4000 6000 8000
Test frequency (Hz)

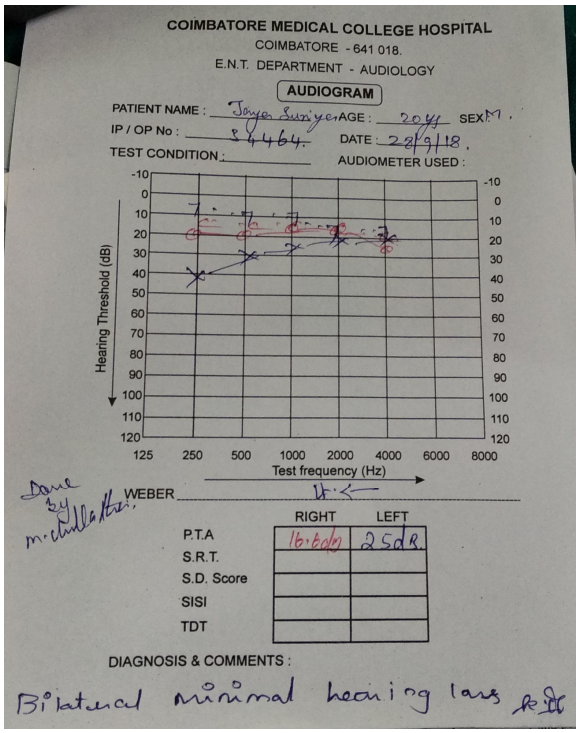
Done by M. Chilla Hari

WEBER Rt. Lt.

	RIGHT	LEFT
P.T.A	16.6db	35dB
S.R.T.		
S.D. Score		
SISI		
TDT		

DIAGNOSIS & COMMENTS :
Rt - Normal hearing
Lt - Mild conductive hearing loss

POST OPRATIVE PTA (CARTILAGE OSSICULOPLASTY)



COIMBATORE MEDICAL COLLEGE HOSPITAL
COIMBATORE - 641 018.
E.N.T. DEPARTMENT - AUDIOLOGY

AUDIOGRAM

PATIENT NAME : Jenja Suriya AGE : 20yrs SEX : M
IP / OP No : 34464 DATE : 22/9/18
TEST CONDITION : AUDIOMETER USED :

Hearing Threshold (dB)
-10 0 10 20 30 40 50 60 70 80 90 100 110 120
125 250 500 1000 2000 4000 6000 8000
Test frequency (Hz)

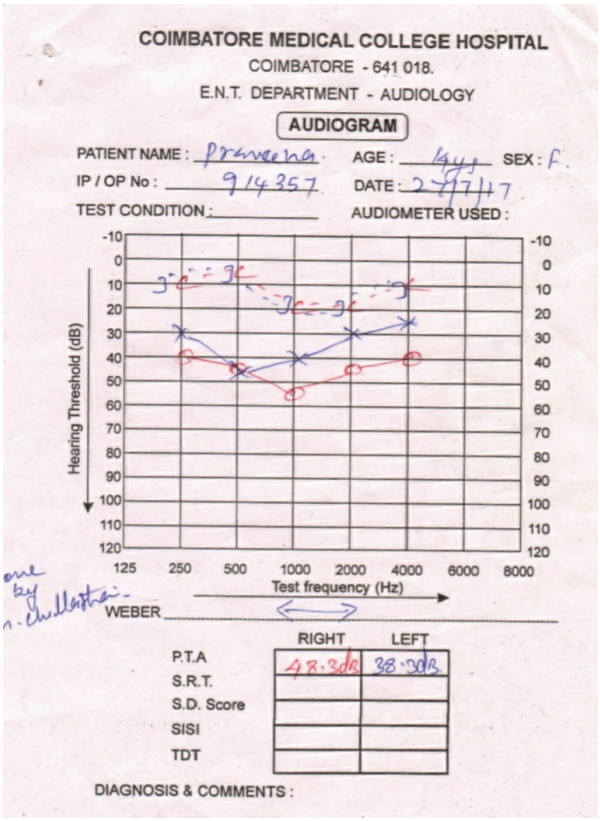
Done by M. Chilla Hari

WEBER Rt. Lt.

	RIGHT	LEFT
P.T.A	16.6db	25dB
S.R.T.		
S.D. Score		
SISI		
TDT		

DIAGNOSIS & COMMENTS :
Bilateral minimal hearing loss

PRE OPERATIVE PTA



POST OPERATIVE PTA (PORP OSSICULOPLASTY)